MEDICARE COVERAGE DECISIONS AND BENEFICIARY APPEALS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

APRIL 22, 1999

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MEDICARE COVERAGE DECISIONS AND BENEFICIARY APPEALS

THURSDAY, APRIL 22, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 1:11 p.m., in room 1100, Longworth House Office Building, Hon. Bill Thomas (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
April 12, 1999
No. HL–4

CONTACT: (202) 225–3943

Thomas Announces Hearing on Medicare Coverage Decisions and Beneficiary Appeals

Congressman Bill Thomas (R–CA), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on how the Health Care Financing Administration (HCFA) makes decisions regarding Medicare covered services and what opportunities exist for seniors to appeal those decisions. The hearing will take place on Thursday, April 22, 1999, in the main committee hearing room, 1100 Longworth House Office Building, beginning at 1:00 p.m.

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Coverage is an important concept in understanding Medicare benefits: the Social Security Act requires that all medical services be "reasonable and necessary" for the treatment of an illness or injury. HCFA and its private-sector contractors (known as fiscal intermediaries and carriers) have broad discretion to make Medicare coverage decisions. In some cases, the agency makes sweeping National Coverage Determinations (NCD). Under current law, beneficiaries can appeal many Medicare decisions but they are largely foreclosed from appealing NCDs.

The current Medicare appeals system can best be characterized as a patch-work—a large number of independent appeal processes addressing a multitude of diverse issues. Medicare appeals are divided into three distinct parts: Medicare Part A (generally hospital inpatient stays), Medicare Part B (generally physician services), and Medicare managed care. Each of these three parts is, in turn, broken into distinct sub-parts, one for beneficiaries seeking covered services and others for medical providers seeking reimbursement for services. HCFA uses a number of levels of review, including governmental contractors (fiscal intermediaries and carriers), review panels (Provider Reimbursement Review Board, Peer Review Organizations, Departmental Appeals Board) and judicial officers (Administrative Law Judges and Federal U.S. District Courts).

The current appeals processes stem from the Omnibus Budget Reconciliation Act of 1986 (OBRA86) in which Congress made several important reforms to the Medicare appeals system. Since then, the appeals process has become increasingly complex and time-consuming. An increase in the number and complexity of appeals calls into question the adequacy of the current system. Many Supreme Court and Federal court decisions concerning the Medicare appeals system have raised basic questions about its fundamental fairness to beneficiaries and providers.

In announcing the hearing, Chairman Thomas stated: "At a time when the Administration is seeking swifter appeals in private health plans, it is only fitting that we consider how various appeals are handled in governmental programs like Medicare. There are too many people, including Federal bureaucrats and governmental contractors, making coverage decisions without being held accountable. America's seniors deserve a meaningful opportunity to question these decisions."

FOCUS OF THE HEARING:

This hearing will analyze the processes available for seniors and medical providers to appeal payment and coverage determinations under Parts A and B of the Medicare program.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Any person or organization wishing to submit a written statement for the printed record of the hearing should submit six (6) single-spaced copies of their statement, along with an IBM compatible 3.5-inch diskette in WordPerfect 5.1 format, with their name, address, and hearing date noted on a label, by the close of business, Thursday, May 6, 1999, to A.L. Singleton, Chief of Staff, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. If those filing written statements wish to have their statements distributed to the press and interested public at the hearing, they may deliver 200 additional copies for this purpose to the Subcommittee on Health office, room 1136 Longworth House Office Building, by close of business the day before the hearing.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be submitted on an IBM compatible 3.5-inch diskette in WordPerfect 5.1 format, typed in single space and may not exceed a total of 10 pages including attachments. Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. A witness appearing at a public hearing, or submitting a statement for the record of a public hearing, or submitting written comments in response to a published request for comments by the Committee, must include on his statement or submission a list of all clients, persons, or organizations on whose behalf the witness appears.

4. A supplemental sheet must accompany each statement listing the name, company, address, telephone and fax numbers where the witness or the designated representative may be reached. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and the public during the course of a public hearing may be submitted in other forms.

Note: All Committee advisories and news releases are available on the World Wide Web at "http://www.house.gov/ways_means/".

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202–225–1721 or 202–226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman THOMAS. The Subcommittee will come to order.

As we begin this hearing on Medicare coverage, I am pleased to announce that the Health Care Financing Administration has finally been able to publish, very coincidentally today, a regulation which sets forth the administrative process for Medicare coverage. I really do not think it is mere coincidence that HCFA published this on the same day as this Subcommittee's hearing. If I had known that was the operating procedure, I would have scheduled this hearing a month earlier.

One year ago this week, the Ways and Means Subcommittee on Health convened a hearing to examine the rights of patients to appeal benefit decisions in both the private and the public health programs. Since that time, appeals decisions have been monitored by Members of this Subcommittee, and we have drafted various pieces of legislation to improve the way patients' appeals are heard in both the fee-for-service and the managed care area.

One legislative proposal, H.R. 4250, the Patient Protection Act, was passed by the House in July of last year. My colleagues on the other side the aisle declined to support that bill based in part, I believe, on arguments that they presented that the bill did not provide speedy enough access to judicial review. And yet if I have learned anything over the last year it is that private health insurance even under current law allows for quicker access to judicial review than does the Medicare Program.

Today, we are going to examine the patient appeals process within the Medicare Program, and I will direct your attention—you may or may not be able to see it; my assumption is that we have copies available to you—on the Medicare appeals process, and what this schematic chart basically shows you is that Medicare requires an individual to run a gauntlet of administrative appeals, first, to a government contractor, then to an agency advisory board, then to an administrative law judge, then to the Department Appeals Board, and then only after a "final decision" by the Secretary is there a limited court or judicial review.

As I said a year ago at our first patient appeals hearing, due process means many things. To legal scholars, it is term of art meaning the technical process by which legal rights are enforced, but in a larger sense, when we use the term "due process," it means simply the opportunity to be heard; the chance to air grievances objectively, get on the record so that you can let people see what has been happening.

Today, we will examine the opportunity seniors have to challenge decisions made in the Medicare Program. I would like to note that the administration has had, in my opinion, difficulty in wrestling with this decision. The best example of this is the administration's handling of a Federal circuit decision known as the *Grijalva* case. The 9th circuit decided that the rights of seniors were not being given sufficient weight in Medicare HMOs. The administration, I think, to say the least, was split as evidenced by an article in the New York Times on January 22 over whether the administration should challenge the court's decision to improve rights for seniors.

One internal administration memo, quoted in the paper, said, "The Department's position, challenging the court order, could be seen as inconsistent with the administration's stated policy of expanding consumer protections."

Today, we will also be examining the Medicare coverage process. Appeal rights within Medicare are inextricably intertwined with the Medicare coverage process. Coverage is an important concept in understanding Medicare benefits. The Social Security Act, section 1862 says that Medicare covers only medical services that are "reasonable and necessary" for the treatment of an illness or an injury, and yet the definition of reasonable and necessary is left largely to the Health Care Financing Administration and its private sector contractors, known as fiscal intermediaries and carriers. Together, they have broad discretion to make Medicare coverage decisions. It has been indicated to me that the vast majority of the decisions, upward of 90 percent, are made locally by contractors. In all other cases, the Health Care Financing Administration makes national coverage determinations usually involving access to very expensive high-tech medicine. Under current law, beneficiaries may appeal local Medicare decisions, but they cannot generally appeal HCFA's national coverage decisions, and I am interested, if at all possible today, in learning why that is the case.

As many of you know, Members of this Subcommittee have played a leading role in prodding the Health Care Financing Administration to develop a more deliberative coverage process. In 1997, this Subcommittee learned, as a result of a congressional investigation, that HCFA's Technology Advisory Committee, or TAC, was meeting in closed-door sessions in violation of Federal statute. Since then, HCFA has dumped TAC and revamped its advisory committee process, and yet the current HCFA coverage decision-making process is still made with little input from seniors, physicians, medical technology manufacturers; in short, those directly affected by those decisions.

I understand that the private sector is, in many instances, such as pharmaceuticals, becoming much more efficient in Medicare in approving access to the most advanced care. While HCFA's proposal for a new coverage process is, in effect, a good system, the new proposal will still not address the local coverage process. Instead, the new proposal focuses exclusively in improving the national coverage process, and I am interested in learning more about this new coverage regulation which we just received. I tried to read briefly through it, and I did note that on page 10, it was reinforcement of the carrier or the intermediary making local decisions.

As we prepared for this hearing, I have heard a great deal of frustrations from constituents about the current Medicare appeals and coverage process. I continue to believe that this is an overly muddled process. I do hope that we can look at fundamental reforms. Medicare commission, premium support model, and others would be the best way to free ourselves from this hopelessly muddled structure, but, until then, we will work to improve the current process.

Let me end—before I hand off to my colleague from California, my friend, Mr. Stark—a concern that he and I share since we both signed the letter that was addressed to the Administrator on Feb-

ruary 2, 1999 in which we were concerned about the fact that contractors have the authority to enforce coverage policy and that they are also being given the authority to establish the very policy that they enforce and that, at the very least, establishing and enforcing coverage policy should be separate. In a letter in answer to that February 2 letter, received April 20—2 days ago—the administrator, in responding to our letter, said "In the long run, I believe the best way to administer local coverage is to separate the development of the coverage decisions or policies." I guess they are for agreeing with the concern that the Ranking Member and the Chairman showed but that I don't see any evidence of that reflected in the proposal or the notice that has been submitted, and I would also look forward to some indication, then, about what the Administrator may have meant, to the best of anyone's ability to interpret, what "in the long run" means.

[The opening statement follows:]

Opening Statement of Hon. Bill Thomas, a Representative in Congress from the State of California

As we begin this hearing on Medicare coverage, I am happy to announce that the Health Care Financing Administration (HCFA) has finally been able to publish *today* a regulation which sets forth the administrative process for Medicare coverage. I do not think it is mere coincidence that HCFA published this on the same day as this Subcommittee's hearing. If I had known that a hearing was all it would take to get this regulation published, I would have scheduled the hearing a month ago.

One year ago this week, the Ways & Means Subcommittee on Health convened a hearing to examine the rights of patients to appeal benefits decisions in both private and public health programs. Since that time, Members of this subcommittee have been vigorously drafting various pieces of legislation to improve the ways patient appeals are heard in both fee-for-service and managed care.

One legislative proposal, H.R. 4250, the Patient Protection Act was narrowly passed by the House in July 1998. My colleagues on the aisle opposite declined to support that bill, based largely on the belief that the bill did not provide speedy enough access to judicial review. And yet, what I have learned in the past year is that private health insurance, even under current law, allows for quicker access to judicial review than does the Medicare program. Today, we are going to examine the patient appeals process within the Medicare program.

I direct your attention to this enlarged schematic which shows the current Medical appeals processes.

As you can see, Medicare requires an individual to run an entire gauntlet of administrative appeals, first to a government contractor, then to an agency advisory board, then to an Administrative Law Judge, then to the Departmental Appeals Board, and then—only after a "final decision" by the Secretary—is there limited judicial review.

As I said one year ago, at our first patient appeals hearing, "due process means many things." To legal scholars, it is a term of art meaning the technical process by which legal rights are enforced. In a larger sense, due process means simply the opportunity to be heard, the chance to air grievances, objectively and on-the-record.

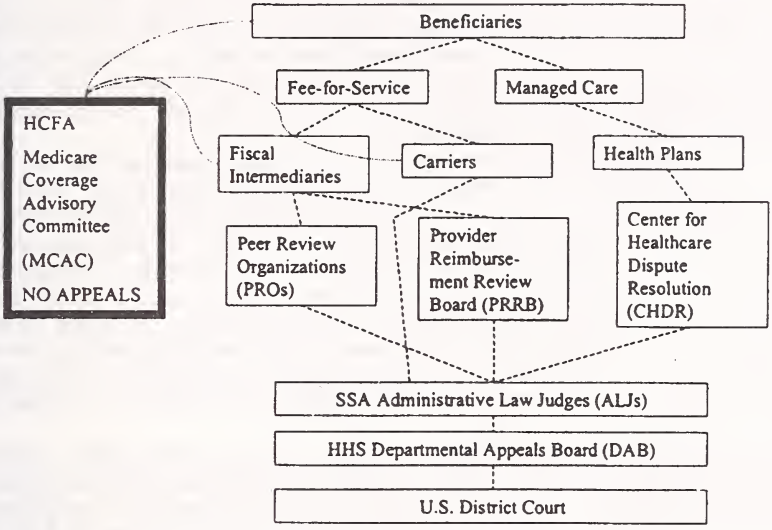
Today, we will examine the opportunities seniors have to challenge decisions made in the Medicare program. I would like to note that the Administration has had great difficulty wrestling with this issue.

The best example of this is the Administration's handling of a Federal Circuit Court decision known as Grivalja (pronounced: *GRA-val-ha*). The Ninth Circuit decided that the rights of seniors were not being given sufficient weight in Medicare HMOs. The Administration was bitterly split—as evidenced by an article in the New York Times on January 22—over whether the Administration should challenge the Court's decision to improve rights for seniors. One internal Administration memo quoted in the paper said, "The Department's position [challenging the Court order] could be seen as inconsistent with the Administration's stated policy of expanding consumer protections...."

Today, we will also be examining the Medicare coverage process. Appeal rights within Medicare are inextricably intertwined with the Medicare coverage process. Coverage is an important concept in understanding Medicare benefits. Social Secu-

rity Act section 1862 says that Medicare covers only medical services that are "reasonable and necessary" for the treatment of an illness or injury.

Medicare Appeals Process



And yet, the definition of "reasonable and necessary" is left largely to the Health Care Financing Administration (HCFA) and its private-sector contractors (known as "fiscal intermediaries" and "carriers"). Together, they have broad discretion to make Medicare coverage decisions. Most decisions—90%—are made locally by contractors. In all other cases, the Health Care Financing Administration (HCFA) makes "National Coverage Determinations"—usually involving access to high-tech medicine.

Under current law, beneficiaries may appeal local Medicare decisions but they cannot generally appeal HCFA's "National Coverage Decisions." I am interested in learning why that is the case.

As many of you know, Members of this Subcommittee have played a leading role in prodding the Health Care Financing Administration (HCFA) to develop a more deliberate coverage process. In 1997, this Subcommittee learned, as a result of a congressional investigation, that HCFA's Technology Advisory Committee (TAC) was meeting in closed-door sessions, in violation of Federal statute. Since then, HCFA has revamped its advisory committee process.

While HCFA's proposal for a new coverage process is an improvement over the current system, the new proposal—from what I understand from initial reports—will still not address the local coverage process. Instead, the new proposal focuses exclusively on improving the national coverage process. I am interested in learning more about this new coverage regulation published by HCFA today.

In preparing for this hearing, I have a heard a great deal of frustration from constituents about the current Medicare appeals and coverage process. I continue to believe that a premium support model offers the best means of being freed from this hopelessly muddled situation. However, until then, we shall do our best to improve the current system.

Chairman THOMAS. And, with that, I would turn it over to my colleague from California.

Mr. STARK. Thank you, Mr. Chairman. Thank you for holding this hearing. We would like to work with you to reform the cov-

erage and appeals procedures. I understand they are a mess. My written statement, which I would like to submit in its entirety——

Chairman THOMAS. Without objection.

Mr. STARK. Thank you. My written statement brings up these problems with local coverage and national coverage. I don't think we should set up an appeals system that would force Medicare to pay whatever the providers want for a newly covered service; that would bankrupt us soon. Fee-for-service coverage and appeals are extremely confusing and should be simplified, but so should HMO appeals. In other words, I don't know if we should do fee-for-service changes without doing managed care.

It is my understanding that national coverage policies are not appealable, and that they tend to deal with a particular service, mammography, let us say. I am not sure that we should appeal that. We don't allow appeals of FDA decisions. Those are—or I hope they are—scientific decisions that are made with the best scientific knowledge available as to whether or not a particular procedure is useful. So, local decisions, it seems to me, are more based on whether the service which has been approved nationally is used appropriately, if it is used too frequently or if it is not used for the proper diagnosis. That makes more sense, although, as you point out, it is terribly confusing.

So, I am glad you are willing to enter into this discussion. I hate to remind you that if we move to premium support, you won't have to do this anymore. Under premium support none of the providers will ever be able to appeal anything. But, I don't know as I have to put any red meat out in front of them; somebody who is bound and determined to be the junkyard dog in this fight. So, with that, I will assume that we have not reached a conclusion quite yet in premium support and that this hearing today will be somewhat useful for at least the near future. Thank you, Mr. Chairman.

[The opening statement and attachments follow:]

Opening Statement of Hon. Fortney Pete Stark, a Representative in Congress from the State of California

Mr. Chairman:

Today, the Committee is examining two of the functions performed by Medicare contractors—establishing coverage policies and hearing appeals. This hearing will help us to understand the need for broader contracting reform in Medicare as we consider the functions that contractors perform.

COVERAGE

More than 100 Medicare contractors are engaged in establishing Medicare coverage policies, and the result is inconsistency in those policies. Carriers determine local Part B coverage policies, PROs determine hospital coverage policies, and Fiscal Intermediaries determine coverage policies for SNFs and home health agencies. We need to restructure and simplify this process and reduce the number of contractors involved in establishing local Medicare coverage policies.

Beginning in 1987, HCFA has tried several times to publish rules governing the process used in establishing national coverage policies, and they are now trying once again. I applaud their efforts and urge them on. HCFA is also moving toward scientific, evidenced-based Medicare coverage policy making, and I also agree with that change.

We also need published guidelines governing local coverage policies. For example, if local coverage of a technology is needed to gain experience with it, then we should also ensure that Medicare beneficiaries are protected and that we obtain the valid and reliable data to evaluate the safety and effectiveness of the technology. We should not grant general authority to experiment on Medicare beneficiaries.

HCFA plays little role in coordinating and overseeing local coverage policies, and does not publish them. And national Medicare coverage policies should be consolidated and published in a single Medicare coverage manual, rather than the many manuals in which they are now published.

Managed care plans that contract with Medicare are required to comply with local coverage policies, but they find it difficult to learn what the local policies are. In the age of the internet, Medicare coverage policies should be published and readily available for all to see on the internet.

Mr. Chairman, on February 2, you and I wrote to the HCFA Administrator asking that HCFA management of local Medicare coverage processes be transferred from the HCFA office that oversees the Medicare fraud and abuse programs to the office that determines national Medicare coverage policies. On Tuesday, we received a response to our letter. In that response, HCFA Administrator, Nancy-Ann Min DeParle, said, "In the long run, I believe the best way to administer local coverage policy is to separate the development of the coverage decisions or policies, (which focus on whether a given service should be covered), from the development of local medical review policies, (which focus on the appropriate utilization of a service in that locality and program integrity issues)."

Mr. Chairman, that is precisely the position that you and I took in our letter to the Administrator. We also said that these two functions should be separated. Coverage policy should be a function of quality-of-care, and medical review is a function of program integrity.

The HCFA Administrator goes on to say, "I want to move in this direction as Medicare program management resources permit." So the issue seems to be funding. I would ask what additional funding HCFA needs to separate these two functions now, and I would like to work with you, Mr. Chairman, to ensure that HCFA receives the funds needed to make this change now.

Coverage vs. Payment

Mr. Chairman, let me be clear—Medicare coverage policy and Medicare payment policy are two distinctly different things. Once Medicare decides to cover a new product, it must decide what to pay for the product. Medicare should not simply accept the "sticker price" that manufacturers set for new products. Instead, Medicare should be a prudent purchaser, setting reasonable payment amounts for products. Then, manufacturers can make business decisions whether they want to sell their products to Medicare or not. I believe that they will want to sell their products for reasonable prices to Medicare.

Indeed, last year, several local Medicare carriers implemented a "least costly alternative" payment policy concerning two Medicare covered prescription drugs—Lupron and Zoladex—used in the treatment of prostate cancer. One of these drugs (Lupron) was much more expensive than the other (Zoladex). Since medical experts concluded that these drugs were equally suitable alternatives, Medicare carriers decided to cover both drugs, but to pay only at the price of the lower-priced drug. HCFA then found that the price of the higher-priced drug suddenly dropped, because the company would rather sell its product at a more reasonable price than not sell it at all.

A similar thing happened for the drug, TPA, used in the treatment for heart attacks. The manufacturer originally tried to pressure HCFA into increasing the hospital DRG payment amount to reflect the "sticker-price" that the manufacturer set for the drug, but HCFA refused. Over time, hospital lengths of stay were reduced, and other lower-priced drugs were introduced of equivalent medical value; so HCFA has never had to increase the DRG payment for TPA. This situation taught us the lesson that HCFA should not be too quick to accept manufacturer "sticker-prices."

Using comparisons of costs and effectiveness of technologies in determining Medicare payment amounts is one way to incorporate "cost-effectiveness" into Medicare coverage policy making. Rather than using "cost-effectiveness" in establishing the coverage policy, it is used in setting the payment amount.

Appeals

Similarly, Medicare appeals processes need updating. Appeals processes in traditional, fee-for-service Medicare are complex and confusing, and are quite different from those mandated for managed care. Indeed, it can be argued that Medicare beneficiaries have fewer rights and protections in traditional, fee-for-service Medicare than in managed care.

In managed care, beneficiaries have a right to know in advance of any service whether the service will be covered by Medicare or must be paid for by the beneficiary. That right does not exist in traditional Medicare, where contractors decide

whether a service is covered only after a claim is submitted. Often, beneficiaries are then required to pay for services that they thought would be covered by Medicare.

Similarly, in managed care, beneficiaries have a right to an external appeal if Medicare coverage is denied; but not in traditional Medicare, where the Medicare contractor that establishes the coverage policy also hears the appeals on it. We also need to reduce the number of contractors involved in the appeals process in traditional Medicare, and consider the need for an external appeals process.

In traditional Medicare, minimum dollar thresholds are required before appeals are permitted—for example, $100 for appeals of Part B services to carriers. No such minimum thresholds apply for managed care, and beneficiaries are permitted to appeal all denials of care. Denials of services, even for "only" $50 mean a lot to many Medicare beneficiaries. Similarly, a minimum dollar threshold of $500 must be reached to appeal Part B claims to Administrative Law Judges (ALJs), but only $100 for Medicare+Choice.

Another problem concerning traditional Medicare appeals processes is HCFA's lack of requirements for providers to give beneficiaries "notices of noncoverage" and "advance beneficiary notices (ABNs)." Medicare beneficiaries must be adequately informed both of their appeal rights and of services that are not covered. On January 25, I wrote to the Secretary asking her to ensure that beneficiaries in traditional Medicare are given these protections. I have not yet received a response to my letter.

I do not mean to imply that Medicare managed care appeals processes are without problems. Last week, the GAO released two studies describing problems involving beneficiary information and appeals processes in Medicare+Choice plans. GAO found that beneficiaries are often given inaccurate and incomplete information by the plans—both about services that are covered and about their appeal rights—and that their ability to appeal is limited by the incorrect information provided to them. This situation is unacceptable must be corrected.

Medicare law has never permitted appeals of national coverage determinations, and I question the wisdom in permitting such appeals now. Just as the FDA has no appeals mechanism for its scientific determinations, I question whether Medicare should have an appeals mechanism for its national coverage policies. A governmental entity with scientific expertise must be responsible for establishing policies that affect Medicare spending—often large increases in spending. Currently, that responsibility is shared by the Congress and HCFA. On a practical level, I question what body would be technically qualified to consider such appeals.

Mr. Chairman, we all want Medicare to be well administered, and I would like to work with you on the improvements needed in administering the coverage and appeals processes in Medicare.

Thank you, Mr. Chairman.

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

February 2, 1999

The Honorable Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration
U.S. Department of Health and Human Services
Room 314-G
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Nancy-Ann:

We are writing to express our concern over a decision by the Health Care Financing Administration (HCFA) involving the Medicare coverage process. We are concerned that HCFA has divided responsibility over Medicare coverage decisions between the Office of Clinical Standards and Quality and the Medicare Integrity Program (MIP).

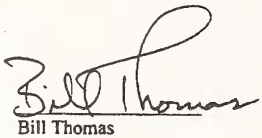
We believe that, absent a compelling argument, all coverage decisions should be placed in the Office of Clinical Standards and Quality and should not be considered part of MIP. Currently, the vast majority of coverage decisions are made at the local level by Medicare carriers. National coverage decisions are made by HCFA's Office of Clinical Standards and Quality, in conjunction with an advisory panel of experts.

Conversely, MIP was established as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and gives HCFA specific contracting authority to enter into contracts with private-sector organizations to fight fraud and abuse in the Medicare program. On December 14, 1998, you sent a report to the Appropriations Committees regarding MIP expenditures. In that report, you informed Congress that the MIP program would have increased responsibility over the coverage process. We have also learned that HCFA has informed potential MIP contractors that MIP contractors will have a greater role in making local Medicare coverage policies.

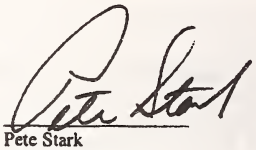
We are concerned by these developments. Medicare coverage policy should be a quality-of-care concern, not a payment or integrity concern. The proposed rule for the Medicare Integrity Program, which you published on March 20, 1998, listed the functions of the Medicare Integrity Program contractors, and no mention was made of any role concerning Medicare coverage policy. Because these contractors will have the authority to enforce coverage policy, we are concerned that they are also being given the authority to establish the policy. Establishing and enforcing coverage policy should be separate.

As you are aware, the Ways and Means Health Subcommittee will conduct a hearing on February 11 regarding HCFA management issues, and we hope that we will be able to explore this issue further at that time.

Sincerely,



Bill Thomas
Chairman



Pete Stark
Ranking Member

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

APR 20 1999

The Honorable Pete Stark
Ranking Member, Subcommittee on Health
Committee on Ways and Means
House of Representatives
Washington, D.C. 20515

Dear Mr. Stark:

Thank you for your letter concerning the development of Medicare coverage decisions by the Health Care Financing Administration (HCFA), and Medicare Integrity Program contractors.

The issues you raise are both important and complicated, and I have raised some of the same questions myself. Therefore, in order to more fully respond to your concerns, I want to provide you with some historical background on Medicare coverage policy, discuss the relationship of national policy to local medical review policy, and finally, explain how these first two items relate to the Medicare Integrity Program.

Background

In 1965, during its consideration of the Medicare bill, the Congress decided that private insurers and the Blue Cross and Blue Shield Association should play an important role in both launching the program and providing expertise in the processing of Medicare claims. As a result, as you know, the Medicare law establishes these groups as the contractors (carriers and intermediaries) that process and pay Medicare claims.

Given the large volume of claims expected (although small by today's standards), the Congress recognized that these contractors would have to make decisions on the proper disposition of claims. There was a recognition then, as there is now, that health care practices are local and there is an acceptable local variation which needed to be accounted for in the administration of the Medicare program. Thus, as I understand it, local medical review and policy-making on what constitute "reasonable and necessary" services in local communities was the result of a deliberate policy choice made by the Congress in determining how to administer the Medicare program.

National and Local Policy

Medicare coverage is a decision, based on clinical and scientific evidence, on what medical

services Medicare should pay for within the benefit framework set by Congress. It is about covering or not covering services, or covering services with certain clinical restrictions to allow Medicare beneficiaries the best quality of care, but also ensuring that we do not pay for more services than are medically needed.

National coverage policy is developed by HCFA to define whether and under what circumstances certain services are covered. Such policy is published in Federal Register regulations/notices, contained in HCFA rulings, or issued as program instructions. The provider community is notified of the national coverage policy and the policy is binding on our Medicare contractors. In addition, such national policies may establish ceilings or floors for Medicare coverage of an item or service. Medicare contractors must stay within these ceilings and floors.

In contrast, local medical review policy (which is a term that has come to encompass both local coverage policy and local review policy) is developed when there is no national coverage policy or when there is a need to further interpret a national Medicare coverage decision for the purpose of deciding whether a service is covered and, therefore, whether a payment should be made. Local medical review policies are developed by Medicare Contractor Medical Directors, whose positions are funded through the Medicare Integrity Program, with the support of advisory councils composed of provider and supplier representatives. The Contractor Medical Directors' responsibilities include oversight of all medical review functions, including the development of medical review policies.

Local policies may be developed for many reasons. In the course of conducting medical review, contractors may become concerned about local practices in utilization, coding, or documentation of services. They may wish to focus on areas of concern and introduce computer edits or review protocols to more closely monitor a class of claims. Similarly, contractors may learn of problems in other parts of the country and seek to prevent similar problems in their jurisdiction by issuing local medical review policy. Also, providers and suppliers may ask contractors to issue local medical review policy in order to clarify whether certain services can be billed and paid (i.e., covered by being medically necessary and reasonable). Contractors develop and publish local medical review policy, outline concerns, communicate on what is covered or not covered as well as on how they plan to review and accept claims, and what providers and suppliers should do in order to ensure payment.

The Medicare Integrity Program

All local policy developed by our contractors must balance our concerns to protect the Medicare trust fund with the need for high quality care and appropriate access to care. There is a healthy tension among these overarching principles that must be respected whether policy is made at a national or local level.

The Medicare Integrity Program (MIP) provides guaranteed funding for certain specified purposes, including medical review. Under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which established MIP, we may also contract competitively under Federal Acquisitions regulations with contractors to perform these functions. In essence, under the MIP statute, we can procure medical review in a more competitive manner, rather than relying exclusively or even primarily on our current contractor community. The MIP statute does not change what medical review is; rather, it expands the range of entities that may perform it.

Our published regulation on MIP discusses the functions that special MIP contractors can perform. These functions include medical review, as specified by the statute. Our rule defines medical review in ways consistent with longstanding past practice as ". . .the processes necessary to ensure both the appropriate utilization of services and that services meet professionally recognized standards of care. . . ." Issuing local medical review policies is an integral part of medical review. It has always been paid for and developed with medical review funds, as part of the program safeguard budget prior to HIPAA, and later MIP. Additionally, our published scope of work, in which we outlined the functions of a full Payment Safeguard Contractor, detailed local medical review policy as part of the medical review activities.

The current contracting strategy for the implementation of Payment Safeguard Contractors calls for an incremental approach. In the near term, we plan to issue task orders for Payment Safeguard Contractor work that provides for innovative approaches to program safeguards work, in ways that minimize disruption to current contractors' workload and Y2K efforts. At this time, we are not looking to the Payment Safeguard Contractors to develop medical review policies. Instead, any review of claims and supporting documentation must follow the local medical review policy of the affiliate contractor.

In the long run, I believe the best way to administer local coverage policy is to separate the development of the coverage decisions or policies, (which focus on whether a given service should be covered), from the development of local medical review policies, (which focus on the appropriate utilization of a service in that locality and program integrity issues). I want to move in this direction as Medicare program management resources permit. Toward this end, we may, in the future, issue Payment Service Contractor task orders for all medical

review functions in a particular area. If we do this, the carrier medical director will work for this Payment Safeguard Contractor and have oversight over development of all local medical review policy, similar to the arrangement that exists today. We expect, however, that we will have two distinct units functioning within the Payment Safeguard Contractor, one for the development of local coverage policies, and one for the development of local medical review policies. Consistent with my long-range goal, this allows for separate consideration of these two functions while maintaining the necessary link and tension between them through the common management by the carrier medical director.

I hope this information responds to your concerns. If your would like to discuss this matter further, please call me or have your staff contact HCFA's Chief Clinical Officer, Jeffrey Kang, M.D., at (410)786-6841 or our Director of Program Integrity, Penny Thompson, at (410) 786-5704. A similar letter is being sent to the Honorable Bill Thomas.

Sincerely,

Nancy-Ann Min DeParle
Administrator

COMMITTEE ON WAYS AND MEANS

U.S. HOUSE OF REPRESENTATIVES
WASHINGTON, DC 20515

SUBCOMMITTEE ON HEALTH

January 25, 1999

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Dear Madam Secretary:

In November of 1998, you and the HCFA Administrator sent to every Medicare beneficiary in the nation a bulletin -- "Medicare and You" -- providing important information about Medicare. Included on page 5 of that bulletin was a listing of Medicare Patients' Rights (copy attached). Among those rights, you informed Medicare beneficiaries that they have "the right to information about what is covered and how much you have to pay." In the bulletin, you informed Medicare beneficiaries, "You have these Medicare rights whether you are in the Original Medicare Plan or in another Medicare health plan." As I have told you in a separate letter, I applaud and support your actions to inform Medicare beneficiares of their rights.

Madam Secretary, although "the right to information about what is covered and how much you have to pay" has been included in regulations for many years for Medicare managed care enrollees, this protection has been missing or greatly eroded in Medicare regulations for beneficiaries in original, fee-for-service Medicare. Regulations were promulgated during the Reagan Administration requiring managed care plans contracting with Medicare to provide Medicare beneficiaries a "notice of noncoverage" when they were about to be discharged from a hospital stay, informing them that continued hospitalization would not be covered and that the beneficiary would be required to pay for a continued stay. However, similar regulations have never been promulgated to protect beneficiaries in original, fee-for-service Medicare. This is a glaring omission in protecting the rights of Medicare beneficiaries.

In addition, HCFA has eroded other rights of Medicare beneficiaries to "information about what is covered and how much you have to pay." The Medicare statute requires providers and

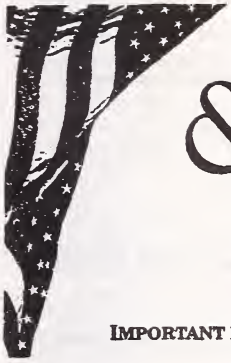
suppliers to inform Medicare beneficiaires in advance whether a service is likely to be covered by Medicare and if not, how much the beneficiary will be required to pay. However, HCFA has applied this statutory requirement only to services considered "not medically necessary," and requires advance beneficiary notices (ABNs) only for those services. As a result, Medicare beneficiaries are sometimes not told until after a service is performed that the service is not covered by Medicare and how much the beneficiary will be required to pay. An example of this problem concerns home health care; Medicare beneficiaries need to be provided an ABN for any home health services that an HHA believes will not be covered by Medicare, and for which the beneficiary will be required to pay.

Madam Secretary, I urge you to address this situation immediately. Please promulgate regulations that keep the promise you made to Medicare beneficiaries in the Medicare bulletin, including beneficiaries in the original, fee-for-service Medicare program. These Medicare beneficiaries deserve to be informed of their rights when they are discharged from a hospital stay, and they deserve to be informed in advance whether a service is likely to be covered by Medicare, and if not, how much they will have to pay. When we are trying to protect Medicare beneficiaries in managed care plans, we must also protect beneficiaries in original fee-for-service Medicare.

Sincerely,

Pete Stark
Ranking Member

PS/tp



Medicare & You

IMPORTANT INFORMATION FROM THE FEDERAL GOVERNMENT

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES
7500 Security Boulevard
Baltimore, Maryland 21244-1850

OFFICIAL BUSINESS
PENALTY FOR PRIVATE USE, $300
Publication No. HCFA-02119
August 1996

BULK RATE
U.S. POSTAGE PAID
PERMIT # G-28
HCFA

Si necesita una copia en Español del boletín "Medicare y Usted," por favor llame gratis al 1-800-318-2596.

This bulletin will give you some basic information about:

HEALTH CARE FINANCING ADMINISTRATION
The Federal Medicare Agency

Do You Need Help to Pay Health Care Costs?

If your income is limited, your State may help pay your Medicare costs, such as your premiums and deductibles. To qualify—

— Your **monthly** income must be less than:

$1,603 for a couple $1,194 for an individual

AND

— Your bank accounts, stocks, bonds, or other resources must be worth less than:

$6,000 for a couple $4,000 for an individual

If you think you qualify for financial help, contact your State or local welfare, social service, or Medicaid agency.

MEDICARE PATIENTS' RIGHTS

As a Medicare beneficiary, you have certain guaranteed rights. These rights protect you when you get health care; they assure you access to needed health care services; and they protect you against unethical practices. You have these Medicare rights whether you are in the Original Medicare Plan or another Medicare health plan. Your rights include:

- The right to protection from discrimination in marketing and enrollment practices.
- The right to information about what is covered and how much you have to pay.
- The right to information about all treatment options available to you.
- The right to receive emergency care.
- The right to appeal decisions to deny or limit payment for medical care.
- The right to know how your Medicare health plan pays its doctors.
- The right to choose a women's health specialist.
- The right, if you have a complex or serious medical condition, to receive a treatment plan that includes direct access to a specialist.

If you believe that any of your rights has been violated, please call the State Health Insurance Assistance Program in your State. The phone number is listed on page 6.

Chairman THOMAS. I thank the gentleman very much, and now, if we could, the Deputy Administrator of the Health Care Financing Administration, Michael Hash, is back with us again, and for a quick return visit, Dr. Kang, who is the Director of the Office of Clinical Standards and Quality. It is nice to have you with us, and any written statements you may have will be made a part of the record, and you can address us in any way you see fit in the time you have available.

[The opening statement of Mr. Ramstad follows:]

Opening Statement of Hon. Jim Ramstad, a Representative in Congress from the State of Minnesota

Mr. Chairman, thank you for calling this important hearing on the Medicare Coverage decision-making process and appeals.

As Co-Chair of the House Medical Technology Caucus, I have been very closely monitoring the Health Care Financing Administration's (HCFA) progress on establishing a formal process for making important coverage decisions. The Caucus has held two important meetings on this topic, one in July of 1998 to review HCFA's draft outline of its proposal and one last February to check on HCFA's progress on the issue.

As we all know, while Medicare law provides for the coverage of various categories of benefits, it does not specify a list of covered technologies and services. That's where HCFA, and this coverage process, come in to play.

Medical technology and innovation play an important role in this critical health care program for America's seniors. As new life-enhancing and life-saving technologies are developed, and more Americans learn about them, the process for making these coverage decisions becomes increasingly important.

As expected, beneficiaries and manufacturers continue to contact Members of Congress on this topic, and a number of positive things have been said about Dr. Kang's efforts, under the leadership of Administrator Min DeParle, to improve the process. Some concerns, however, about specific aspects of the proposal have also been raised. Certainly, the issue of appeals is one of the most frequently discussed concerns.

Thank you again, Mr. Chairman, for calling this important hearing. I look forward to hearing from today's witnesses on how we can further improve the decision-making and appeals processes in the Medicare program.

Chairman THOMAS. Michael.

STATEMENT OF MICHAEL HASH, DEPUTY ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION; ACCOMPANIED BY JEFF KANG, M.D., DIRECTOR, OFFICE OF CLINICAL STANDARDS AND QUALITY

Mr. HASH. Thank you, Chairman Thomas and Congressman Stark, and other distinguished Members of the Health Subcommittee. We want to express our appreciation for the invitation to come here today and to discuss our revised procedures for establishing coverage policy and appeals processes that are available to beneficiaries and to providers.

Medicare beneficiary appeal rights are among the strongest anywhere in this country. Providers and suppliers also have appeal rights under the program and can appeal on behalf of beneficiaries if they become the beneficiary's appointed representative.

In the past year, we have increased efforts to make sure beneficiaries know about their appeal rights. We are working to improve the oversight also of the private plans that contract with Medicare under the Medicare+Choice Program, and we have worked with the Social Security Administration to improve the timeliness and consistency of its administrative law judge rulings on Medicare appeals.

As you know, the average administrative law judge appeal takes over a year now. In order to improve that process, we have undertaken the training of 30 additional administrative law judges that are dedicated solely to Medicare cases, and we are working with our contractors in Medicare to make sure that the materials they provide for ALJ review are sent in a complete and comprehensive manner. Meanwhile, because of our successful crackdown on fraud,

waste, and abuse in the Medicare Program, the total number of appeals is in fact up. To handle the increased workload, the President's fiscal year 2000 budget increases funding for Medicare appeals by $10 million, and we look forward to working with you and other Members of the Congress to secure this necessary increase in funding support for the appeals process.

Also in the past year, we have revised our procedures for establishing national coverage policy. The revised policy is, in our view, more open, accountable, and explicit in every respect, including the right of beneficiaries and other members of the public to request reconsideration of coverage policy decisions. A notice, as you pointed out, Mr. Chairman, describing this new process is on display in today's *Federal Register* and will be published in the *Register* next Tuesday.

The new process establishes clear procedures for how national coverage policy decisions are made. It allows anyone—and I emphasize anyone—to request a decision or a reconsideration of existing coverage policy. Individuals need only submit in writing a request along with new medical and scientific evidence that merits consideration or an analysis of Medicare's decision that demonstrates that we have made a material misinterpretation or have misunderstood or overlooked credible evidence in the evaluation of the coverage decision. We will, of course, regularly review new medical and scientific information ourselves to modify national coverage policy on our own initiative when appropriate.

Our revised process also institutes important timeliness standards, and it keeps interested public parties fully informed through the Internet where we will publish a list of coverage issues that are currently under review; the stage of review that they are in; the major scientific questions that need to be resolved, and an estimate of when the next phase of the process will occur. Most importantly, the new processes guarantee beneficiary input through a new Medicare Coverage Advisory Committee that will hold open meetings and include consumer as well as industry members. Later this year, we will publish, in a proposed rule, the criteria for defining under Medicare when a service or a supply is reasonable and necessary, the statutory standards for coverage under Medicare, and we will invite public comment on our proposed criteria before we finalize them.

We very much appreciate your continuing attention to this important part of the Medicare Program. We look forward to working with you and other Members as we continue to refine our coverage and appeals processes, and Dr. Kang and I would be happy to answer, at this point, any questions that you or other Members of the Subcommittee may have.

Thank you.

[The prepared statement follows:]

Statement of Michael Hash, Deputy Administrator, Health Care Financing Administration

Chairman Thomas, Congressman Stark, distinguished Subcommittee members, thank you for inviting us to testify today about our revised procedures for establishing coverage policy and the appeals processes available to our beneficiaries and medical providers of payment and coverage determinations. We welcome the opportunity to discuss efforts to make our appeals and coverage processes more effective, efficient, and accessible.

Beneficiaries must have prompt recourse if they feel that they are denied needed care. President Clinton is committed to ensuring effective and efficient appeal rights for all Americans. Medicare beneficiaries' appeals rights are among the strongest in the nation, and allow for appeal of virtually any issue regarding provision or payment of services. Providers and suppliers also have appeal rights, and can appeal on behalf of beneficiaries if they become the beneficiary's appointed representative.

In the past year, we increased efforts to make sure beneficiaries are informed of their rights to appeal denials of coverage by Medicare claims processing contractors and Medicare+Choice plans. We are working to improve oversight of Medicare+Choice plan appeals. And we have worked with the Social Security Administration to improve the timeliness and consistency of its Administrative Law Judge rulings on Medicare appeals.

Also in the past year, we have worked to revise our process for establishing national coverage policy so that it is more open, accountable, and explicit in every respect, including the right of beneficiaries and other members of the public to request reconsideration of national coverage policy decisions. The new process will:

- establish clear procedures for how national coverage policy decisions are made;
- allow any individual to submit a formal request for a national coverage decision or reconsideration;
- institute timeliness standards and mechanisms for keeping the public informed about the status of national coverage issues; and
- guarantee beneficiary input through a new Medicare Coverage Advisory Committee that will hold open meetings and include consumer as well as industry members.

Medicare's New National Coverage Determination Process

Medicare is committed to having an open, understandable and predictable process for determining national policy on what specific services and supplies are covered. The law provides for coverage of "reasonable and necessary" medical services and supplies in broad categories, such as hospital, nursing home, and physician care. The Health and Human Services Secretary has legal authority to specify which services, procedures, and devices are covered and under what circumstances.

Medicare claims processing contractors are given discretion to set local coverage policy in areas where national policy has not yet been set. However, when Medicare issues national coverage decisions, they are binding on all Medicare contractors, Medicare+Choice plans, peer review organizations, and, in some cases, Administrative Law Judges.

In making these national coverage determinations, we must strike the appropriate balance between providing timely access to medical advances and ensuring that new technologies and treatments are effective and "reasonable and necessary." To do so, we rely on medical and scientific evidence, including medical literature and data, discussions with medical experts, and technology assessments.

We have been working diligently to improve our national coverage determination process.

- Last September, we held a town meeting to hear a broad spectrum of views on how to improve the Medicare process.
- Last December, we published the charter for a new Medicare Coverage Advisory Committee in accordance with the Federal Advisory Committee Act.
- This month, we are publishing a description of our new national coverage policy-making process in a Federal Register notice.
- And, later this year, we will publish proposed criteria for defining when a service or supply is "reasonable and necessary" in a Federal Register Notice of Proposed Rule Making. We will invite public comment on these proposed criteria before issuing final criteria.

The revised national coverage policy determination process will help ensure that beneficiaries, providers, manufacturers, and other interested public parties are fully informed and can track the status of any determination under consideration. As part of this new process, we will publish on the www.hcfa.gov web site:

- a list of coverage issues under review;
- the stage of review each issue is in;
- the major scientific questions that need to be resolved prior to a coverage decision; and
- an estimate of when the next action will occur.

We also will prepare and maintain a complete and indexed record of all issues that we review for each national coverage decision, including a list of all evidence reviewed, all the major steps taken in the coverage review, and the rationale for

the decisions that were made. A summary of this record also will be provided on the www.hcfa.gov website.

Requesting Reconsideration

The new process makes clear that any member of the public may request a review of a national coverage policy determination at any time. Individuals requesting such a review need only submit the request in writing, along with new medical and scientific evidence that merits consideration, or an analysis of Medicare's decision demonstrating that a material misinterpretation was made in the evaluation of evidence. We will, of course, regularly review new medical and scientific information ourselves to modify national coverage policy on our own initiative when appropriate.

The new national coverage process generally requires us to issue a response to a request for a review of a national coverage determination within 90 days. The request can be referred either to:

- the new Medicare Coverage Advisory Committee; or
- an independent technology assessment body, such as those that contract with the Agency for Health Care Policy and Research.

Otherwise, we will generally notify the requester within those 90 days that:

- national coverage is warranted and will be granted;
- national coverage is not warranted and will not be granted;
- national coverage is warranted, but only under certain limitations;
- coverage will be left to local contractor discretion;
- the request duplicates and will therefore be combined with another pending request; or
- the request duplicates an earlier request for which a decision has already been rendered and available evidence does not warrant reconsideration.

Public input into national coverage policy determinations and reconsiderations is also fostered through the new Medicare Coverage Advisory Committee and its meetings that will be open to the public. The committee will have 120 members and include nationally recognized experts in a broad range of medical, scientific and professional disciplines, as well as consumer and industry representatives. They will be divided into small panels focused on particular issues to review and evaluate medical literature, technology assessments, and other data on the effectiveness and appropriateness of medical items and services. Based on the evidence reviewed, the committee will advise and make recommendations to Medicare. We have already received more than 400 nominations for advisory committee members, and expect it to begin meeting later this year.

APPEALS PROCESSES

Medicare beneficiaries, physicians, and suppliers have extensive rights to appeal individual coverage determinations made by Medicare fee-for-service claims processing contractors or Medicare+Choice health plans. Where there is no national policy, beneficiaries and providers may appeal local claims processing contractor and health plan policy. Where there is national policy, they may appeal how contractors and health plans apply that policy to individual cases. As mentioned above, we are working to make sure beneficiaries know about these rights, to improve oversight of Medicare+Choice plan appeals processes, and to improve the timeliness and consistency of Administrative Law Judge decisions.

Beneficiaries are notified of their appeal rights annually in the Medicare & You handbook, on Medicare Summary Notices and Explanations of Medicare Benefits, in the new standardized Summary of Benefits that we will require Medicare+Choice plans to issue this fall, and on every denial of service notice issued by a Medicare+Choice plan or claims processing contractor. The National Medicare Education Program we piloted last year also includes several ways for beneficiaries to obtain more detailed information about appeal rights, including a toll-free phone line and counselors at State Health Insurance Assistance Programs and many other organizations.

Medicare+Choice Appeals

Appeal rights are important in both managed care and fee-for-service. However, managed care appeals are perhaps more critical to beneficiaries because denials generally come before, rather than after, care is delivered. Beneficiaries must be confident that managed care incentives to reduce unnecessary care will not be allowed to deny them appropriate care.

The Clinton Administration has made appeal rights for Medicare+Choice beneficiaries among the strongest for any managed care enrollees in the country. Since June 1998, plans have been required to:

- respond within 72 hours on appeals of care denials that could jeopardize life, health, or ability to regain maximum function;
- respond within 14 days for initial decisions on all other appeals of service denials, and within 30 days for reconsiderations of appeals;
- state the reasons for a denial in writing;
- use denial notice forms that describe beneficiary appeal rights;
- accept oral requests for expedited appeals;
- follow up verbal notifications in writing within two working days;
- grant automatically all physician requests for expedited appeals; and
- maintain logs and periodically report on requests for expedited appeals.

Since the federal government is the largest purchaser of managed care, our expedited appeals regulation for urgent care cases sets a new, higher standard for the entire managed care industry.

All appeals rejected by plans are automatically forwarded to our independent appeals contractor for independent review, with no monetary threshold or other barrier. This independent contractor, currently the Center for Health Dispute Resolution, is also required to act on expedited appeals within 72 hours, and within 14 days for all other service denials.

Beneficiaries have up to 60 days to appeal an independent review contractor's decision involving at least $100 to Social Security Administration Administrative Law Judges. There is no time limit on Social Security Administration Administrative Law Judge actions. Beneficiaries have up to 60 days to request a review of Social Security Administration Administrative Law Judge decisions by the Health and Human Services Departmental Appeals Board. Finally, beneficiaries have up to 60 days after a Departmental Appeals Board decision to request federal district court review for cases involving at least $1000.

Our beneficiary research tells us that the vast majority of beneficiaries are satisfied with the care Medicare+Choice plans provide and have never filed appeals. Until now we have not gathered statistics on appeals at the plan level. We do know now that in 1998, with more than six million beneficiaries in managed care plans, our independent appeals contractor reviewed 14,745 cases. Of these, 22 percent were decided in the beneficiary's favor. We recognize that the appeals process will become more important in the future when beneficiaries, under the Balanced Budget Act, are no longer allowed to disenroll from plans on a monthly basis.

We are now requiring plans to collect data and, as of January 1, 2000, report to beneficiaries upon request the number of appeals filed, the number decided in beneficiaries' favor, and the timeliness of the process. We will be collecting this and other appeals data ourselves, including:

- how many cases are resolved at the plan level;
- the average and maximum length of time each plan takes to resolve appeals;
- the percentage of plan rulings that occur within the mandated time frames.

This and the other information we will collect will help us:

- better monitor plan performance;
- motivate plans to improve responsiveness;
- determine whether any changes might be needed to improve the system;
- understand the types of services being appealed;
- ensure that beneficiaries have full access to and understanding of their appeal rights; and
- target specific groups who may need additional assistance in understanding appeal rights.

We are surveying beneficiaries who have disenrolled from a Medicare+Choice plan to better understand the extent to which care denials and improper appeals procedures may be involved in decisions to disenroll from plans. We should have our first report of the findings by mid–2000. We also are testing a process whereby beneficiaries can request a disenrollment form via Medicare's toll-free help line, 1–800–MEDICARE (1–800–633–4227), and this will also allow us to ask beneficiaries directly why they are leaving a plan at the time they are leaving. This should provide another helpful way to monitor potential problems with plan appeals information.

We will sample denied claims for further review to ensure that plans are implementing their internal processes in the required manner. Our June 1998 Medicare+Choice regulation makes explicit that plans themselves are ultimately accountable for their appeals processes, regardless of whether they are handled by a subcontractor. And we are considering regulations to establish a standard procedure for handling grievances (complaints involving issues other than denials of service or

payment) to ensure consistency among all Medicare+Choice plans. Other efforts to improve Medicare+Choice appeals protections include:

- consumer testing model language for appeals and care denial forms that we will require Medicare+Choice plans to use once we are sure it is clear and helpful to beneficiaries; and
- revising our protocol for monitoring plans to specifically address whether a plan and its provider groups handle appeals as required.

Fee-for-Service Appeals

Medicare beneficiaries enjoy strong appeal rights in the traditional, fee-for-service program, as well. Most fee-for-service appeals are filed by physicians and suppliers, rather than beneficiaries, over denial of payment after care has been rendered. Physicians and other Part B suppliers have the same right to appeal as beneficiaries if they accept what Medicare pays as payment in full without billing the beneficiary for more than the standard 20 percent coinsurance. Other Part B physicians and suppliers may appeal payment denials based on lack of medical necessity if they are required by statute to make a refund to the beneficiary. Hospitals and other Part A providers also can appeal denials based on medical necessity.

Beneficiaries can file an appeal within 60 days of receiving notice that payment for a claim is being denied. The law requires that our claims processing contractors complete 75 percent of such appeals within 60 days, and 90 percent within 90 days. The average contractor processing time in 1998 was 52.9 days.

Part A disputes can be appealed further to Social Security Administration Administrative Law Judges, where there are no time limits for decisions and where delays are occurring. These appeals must be requested within 60 days of receiving a contractor appeal decision, and must be for claims totaling at least $100. The average processing time for these requests in 1998 was 310 days. Social Security Administration Administrative Law Judge decisions can be appealed within 60 days to the Health and Human Services Departmental Appeals Board. The Departmental Appeals Board can turn down appeals requests, and it can also choose to review cases on its own without a beneficiary or provider request. Health and Human Services Appeals Council decisions involving at least $1000 can be appealed within 60 days in federal district court.

Also under Part A, Medicare beneficiaries have special appeal rights when a hospital discharges them from an inpatient stay against physicians' advise. Such cases are reviewed by Medicare's Peer Review Organizations to make sure incentives in the prospective payment system for shorter hospital stays do not result in beneficiaries being discharged too soon.

Part A providers can appeal reimbursement decisions based on cost reports to Medicare's Provider Reimbursement Review Board. The board's decisions can be appealed to the Health Care Financing Administrator, and those decisions can be appealed in court.

Beneficiaries and Part B physicians and suppliers can file appeals within six months of receiving notice that payment for a claim is being denied. The law requires that our claims processing contractors complete 95 percent of these initial reviews within 45 days. The average contractor processing time in 1998 was 33 days.

Part B disputes for claims totaling at least $100 can be appealed further within six months to claims processing contractors' in-house Hearing Officers, who must complete 90 percent of hearings within 120 days. These requests, on average, took 116 days in 1998. Part B disputes of at least $100 for home health claims and $500 for all other Part B claims can be appealed further within 60 days to Social Security Administration Administrative Law Judges, where there are no statutory time frames for decisions. It took these judges, on average 524 days to issue decisions for cases decided in 1998. Again, Social Security Administration Administrative Law Judge decisions can be appealed within 60 days to the Health and Human Services Departmental Appeals Board. The Departmental Appeals Board can turn down a case or take one on its own, and decisions involving at least $1000 can be appealed within 60 days in the courts.

Improving Administrative Law Judge Appeals

We have been working with our colleagues at the Social Security Administration to improve the timeliness and consistency of its Administrative Law Judge reviews of Medicare appeals. As mentioned above, Part A Administrative Law Judge appeals average 301 days and Part B appeals average 524 days. One reason for these lengthy time frames is that the judges tend to be far more expert in Social Security rules than in Medicare regulations. In fact, only about 5 percent of their caseload involves Medicare disputes. Furthermore, the judges are not bound by Medicare

claims processing contractors' local coverage policy or local policy manuals, though they are bound by Medicare law, regulations, rulings, and national policy. Efforts to improve the process include:

- working with the Social Security Administration to provide special training to 30 judges who will handle the most complicated Medicare Part B cases;
- working to educate judges about how Medicare local policy is created and the underlying reasons for the policy; and
- working with our contractors to make sure that case files forwarded to Social Security Administration Administrative Law Judges are complete and comprehensive.

We are also performing an analysis of the Administrative Law Judge process and will continue discussions with the Social Security Administration about future steps that may be taken.

FISCAL 2000 BUDGET REQUEST

The Administration's highly successful efforts to crack down on Medicare fraud, waste, and abuse have increased the total number of fee-for-service payment denials, and thus increased the total number of payment denial appeals. Also, use of sophisticated statistical sampling in these efforts has lead to cases involving larger numbers of claims and more complex issues. That is why the President's fiscal 2000 budget increases funding for Medicare appeals by $10 million. We look forward to working with you to secure this necessary funding.

CONCLUSION

We are working diligently to ensure that our national coverage policy determination process is open, accountable, and explicit. We are also working to ensure that the appeals rights we provide are strong and the processes fair and efficient. Medicare beneficiaries' and providers' appeal rights are among the strongest in the nation, and we are committed to ensuring that they understand how to exercise these rights. We are also actively engaged with our Social Security Administration colleagues to improve the timeliness and consistency of the Administrative Law Judge level of our appeals processes. We appreciate your interest in these issues, and look forward to working with you as we monitor and continue to refine our coverage and appeals processes. I'd be happy to answer any questions you might have.

Chairman THOMAS. Thank you very much. I am tempted to ask you if the scheduling of this hearing was useful for HCFA to get the notice out of the Office of Management and Budget, but that probably would not be fair to you. So, was this hearing useful? [Laughter.]

Mr. HASH. I am definitely used to that kind of question, Mr. Chairman. As we wrote to you in January, Administrator DeParle indicated that we would be publishing this process, our administrative procedures, in early spring, and we are happy to have met that self-imposed deadline.

Chairman THOMAS. Then I guess—I just wish—I should have scheduled it in March and could have asked you the same question.

One of the questions that I need to ask you even with this revised model is that the current way we do this, obviously, under both A and B is kind of premised on the model that you get a service and then you seek reimbursement, and then if you get turned down, it is after the fact. One, the ideal model would be able to get an answer in advance or at least shorten the timeline, and in the Medicare+Choice plans you have an expedited appeal process, and in your rethinking of the coverage in appeals process, did you move the fee-for-service closer to the expedited process for managed care? If you did, is it the same? And if you didn't, what was the rationale for retaining do first, seek reinforcement second?

Mr. HASH. In the context of the fee-for-service side of Medicare, Mr. Chairman, we process, on average, about 800 million claims a year. So, I know you appreciate that it wouldn't be feasible for us in each and every claim to give an answer in advance of the provision of the service whether or not a particular service for a particular beneficiary will be covered. What we do, however, is provide timely notice of the timeframe in which we must pay our claims in accordance with statutory ceilings that ensure providers are paid on a timely basis. If we don't pay a claim, we have to give a decision that we are not covering it and give the provider or beneficiary an opportunity to appeal that.

With respect to your specific question about have we adjusted any timeframes in the fee-for-service appeals process, those are for the most part, as I understand, Mr. Chairman, are prescribed in statute, and we have not adjusted them. In the case of Medicare+Choice, the statutory provisions on appeals were implemented by regulation June 26, 1998.

Chairman THOMAS. Notwithstanding their being in statute, there are a number of things that the administrator and Secretary have suggested to me that need to be changed in statute. Was there a consideration of presenting to this Subcommittee some concern about those timeliness whether they are in statute or not since if we are going to have be doing some legislative changes in a number of areas, we can do those just as easily; the May 1 date on the Medicare+Choice being an example. If we are going to have to legislate, we can legislate timelines.

Mr. HASH. On the first part, Mr. Chairman, the fee-for-service side of the appeals process, what we have been concentrating on is increasing the timeliness of the administrative law judge review of the appeals. They are too long, and that is why we have put additional resources into the administrative law judge group; that we have begun dedicating 30 of them to Medicare appeals, and we have requested additional money in order to speed the process of the appeals on that side. We would be happy to work with you with regard to further consideration of legislative changes on the appeals side, but we wanted to take the first steps in those areas in which we had discretion.

Chairman THOMAS. Dr. Kang, I made a statement in my opening statement, and I want to see if you either support it or would make an adjustment that would reflect the reality more closely. In terms of the number of the decisions made between national and local—and I have been given the figure of about 90 percent are made locally? Is that accurate or close enough?

Dr. KANG. It is close enough.

Chairman THOMAS. Close enough for government work. Is it, therefore, the quality of the decisions, the scope of the decisions? You, obviously, in rethinking the whole appeals procedure—because your previous procedure was in violation of Federal statute—had an opportunity to review whether or not we wanted to involve local decisions, and my assumption is, based on what I have read in the note, is that you have declined to create a structure fundamentally different than the one that was there. What was the rationale?

Dr. KANG. Mr. Chairman, the concept of the Medicare Program when it was created some 30-odd years ago was to recognize that the practice of medicine is local and that there is tremendous local variation about practice parameters and styles. I actually think that is a very important part of the program to preserve. So, we chose to try to improve the national process first and make it open, accessible, and understandable. I do think that you ask a very important question about what are the implications for the local process, and that will be something that we will be considering and glad to work with you on.

Chairman THOMAS. So, I guess, then, that you probably disagree with Jack Wennberg at Dartmouth University in terms of the variation in regional medical practice is almost always based on undesirable aspects of the practice of medicine instead of quality medicine delivered in different ways. My concern is that the statement that you just made is probably the single strongest reinforcement of overutilization or poor practice of medicine being perpetuated, because we can't move toward a degree of commonality. I can't believe that the variety of differences define "good medicine" automatically.

Mr. MCDERMOTT. Mr. Chairman, could you ask the witnesses to give us an example of what is made at a national level and what is made at a local level—maybe everybody knows, but I am not really sure—so, we get a feeling for what 10 percent and 90 percent really means?

Chairman THOMAS. I will do that. Would you answer my question, because my friend from California wants to get in on this one as well? So, I will go north geographically.

Dr. KANG. I actually agree very much with what Dr. Wennberg has to say. It is not by accident that the coverage policies are in the Office of Clinical Standards and Quality. I think that there are places, in fact, where local variation is not correct, and it represents either under or overutilization. That is where we, quite frankly, should be nationalizing our policies, and that is the purpose of the process that we are creating.

Chairman THOMAS. Can you give us, then, an example, as in part answer to my friend from Washington, what it was that was national and local and what you have now decided to change?

Dr. KANG. As an example, let us take prostate surgery. There is no doubt that prostate surgery should be covered, and so that would be a national decision as a matter of policy.

Chairman THOMAS. "Should be" means that it is not now or it is?

Dr. KANG. No, I am just saying it is now——

Chairman THOMAS. OK, it is. If we are going to get clarification, "should" would be a term that wouldn't be real clear.

Dr. KANG. It is covered.

Chairman THOMAS. It is covered.

Dr. KANG. The question is——

Chairman THOMAS. Procedures.

Dr. KANG [continuing]. The procedures. The question, then, would be what stage of disease would be the appropriate place where you should do prostate surgery versus chemotherapy versus whatever? To the extent that science does not agree, that is left up

to local discretion, and there is variation. Some of that variation is healthy variation, because this is how medical technology can change and diffuse and advance.

Chairman THOMAS. But over time, usually, there develops a consensus position.

Dr. KANG. And, at which point, then, we would end up with, for example, a noncoverage decision for prostate surgery for stage 4 disease, and so that would be—and that is when——

Chairman THOMAS. And that would be a national policy?

Dr. KANG. And that would be a national policy.

Chairman THOMAS. And that is not appealable?

Dr. KANG. And that would be not appealable, because the variation would not be acceptable, because the medical science has agreed that that should not be.

Chairman THOMAS. Well, and that will lead us to another direction in terms of the nonappealability of that national decision, because if you are going to lay your evidence out, there are ways that you need to lay it. That is not enough of an example for you in terms of national versus local? Give us an example today of another area if you will; jump to some area in which there is local decision—the 90/10. Give us a representative example of the 90-, and a representative example of the 10-percent decisionmaking structure.

Dr. KANG. I am not sure I understand the question.

Chairman THOMAS. If 90 percent are made local, give me three examples of the most often made local decisions which would, therefore, be appealable?

Dr. KANG. Many of the local decisions regard the uses of devices and durable medical equipment as such, and this is particularly important because there is actually very little evidence that supports the reasonable and necessary criteria for national decisions.

Chairman THOMAS. But could you wind up with that local decision being yes in one area and no in another.

Dr. KANG. That is true, and then when presumably when it is yes in one area at some point evidence is being gathered that this actually is a very good thing to be covering which then allows us to move toward a national coverage.

Chairman THOMAS. And let us say someone appeals and then when they go all the way up through the structure and the administrative law judge says "No, you are right," and they go back to the local level and they still can't get approval, which will be a testimony coming up on a later panel. How do you get the carrier to follow the appeals process decision if it is different than the decision that they made? What do you do? The carrier choose not to follow it.

Mr. HASH. The carrier, I believe, would be, Mr. Chairman, required to comply if an administrative law judge made a decision on a case that was adjudicated before it. The decision of that case would be binding on the carrier.

Chairman THOMAS. OK. So, legally, you believe it is binding. OK.

Mr. HASH. Now, I might say, Mr. Chairman, if I may, you indicated that if we made a national coverage decision, it would not be appealable. I just want to underscore the fact that the process that is on display today at the *Federal Register* is a process that ac-

counts for an opportunity for reconsideration of any national coverage decision by any party who wants to move it on the basis of new evidence or a material misinterpretation of the evidence on which the coverage decision was made.

Chairman THOMAS. And if it was a decision on the Medicare Coverage Advisory Commission, MCAC—what are you going to be calling this?

Dr. KANG. Medicare Coverage Advisory Committee.

Chairman THOMAS. Well, you are going to shorten at some point so no one will know what you are talking about unless they know the jargon. What is it going to be?

Mr. HASH. We are interested in clarifying our communications, and I think in this case, it doesn't lend itself to an acronym.

Chairman THOMAS. Good, because I heard some earlier ones, and it just wasn't attractive. Can you appeal from the decision there?

Mr. HASH. That is an advisory body. It does not make final decisions; it recommends to the Health Care Financing Administration based on the evidence and judgment that expert clinicians bring to bear and consumer input.

Chairman THOMAS. And if the decision is disagreed by, say, consumers and or practitioners?

Mr. HASH. Then if we make a decision that is contrary to the advice of the advisory committee, then someone could move to reconsider——

Chairman THOMAS. What happens if someone disagrees with the advice of the advisory committee?

Mr. HASH. I am saying we can make a decision that does not agree with the recommendation of the advisory committee, because it is advisory. The advisory committee does not make Medicare coverage policy.

Chairman THOMAS. And what happens if you accept that decision——

Mr. HASH. If we accept this——

Chairman THOMAS [continuing]. And people want to——

Mr. HASH [continuing]. And people want to disagree with it and ask us to reconsider it, there is a procedure for doing that.

Chairman THOMAS. And they have been there once already, and you have decided to make your decision. I guess it is not real comforting to say that you get to run it back through the process again. There used to be a joke about apple juice and people would look at it and say it needs to be run through again. I am just wondering if that isn't similar in terms of——

Mr. HASH. No, I think what we are trying to make here, Mr. Chairman, is a very good faith effort that says that if there is new evidence that we have not considered; if there was a mistake and an omission in our review of the existing evidence, then we are bound to review it and reconsider it.

Chairman THOMAS. Yes, I will let my friend get in on this, but I will tell you one of the more frustrating things is that in a number of areas, what I find is that people believe that the data, the information, the resources that you utilize to make a decision are either incomplete, both in terms of a full picture, or the methodology for collecting the data was flawed, and I have now seen enough reversals in enough areas that I am beginning to believe that there

are some real problems there, and I am just not as comfortable—although I have been through it only once; I am going to go through it a couple of more times—that we have resolved that problem with the structure that you have offered. Do you want to get into this, Mr. Stark?

Mr. STARK. I am concerned by a couple of things that have been said. Dr. Kang suggested we have to preserve local autonomy or differences. My sense is, Doctor, that we would be better off the sooner we can collect enough outcomes research to know with some scientific measure. Do you agree with that?

Mr. HASH. I do, we do.

Mr. STARK. OK, so then you would like to—then local traditions and customs could go the way—OK. Second, you guys have got 30 or 40 people to do all of these coverage policy decisions, and the FDA maybe has 4,000. Why not let FDA decide these things?

Mr. HASH. Mr. Chairman—I mean, Mr. Stark, that is——

Mr. STARK. Say that again, I like to hear that. [Laughter.]

Mr. HASH [continuing]. That is an excellent question——

Chairman THOMAS. I don't mind how often you say it. [Laughter.]

Mr. HASH [continuing]. That is an excellent question. I think it is important to draw a distinction between what the role of the FDA is and what the role of a payer or an insurer like Medicare is. In the case of the former, the FDA, they are making decisions about safety and efficacy of products or procedures as to whether they can be available at all in the American marketplace. That is a very different set of responsibilities than what we have. Once something has been determined to be safe and efficacious by the FDA, then it is a question for us to determine that it is reasonable and necessary for a given Medicare patient that such a device or such a service should be covered.

Mr. STARK. But—stop right there.

Mr. HASH. Yes.

Mr. STARK. But I presume that function has two facets: one, will it make them feel better or get well, and, two, at some kind of cost that we can afford.

Mr. HASH. The first question——

Mr. STARK. Is that correct?

Mr. HASH. Yes, it would be.

Mr. STARK. Then it seems to me that the staff or the structure of the FDA is eminently qualified to make that first decision. They have already decided that it is safe or that it ain't going to kill you or make you grow a third thumb. One would suppose that the same people with the scientific and medical training to make that decision would be able to take the next step and say "We know it is safe, and, further, we know from our tests that—at least in the short run unless the tests have been very long—that it improves the quality of life, or it improves recovery, or whatever it improves. Why HCFA should have to reinvent that or rehash that escapes me, and such cooperation simplifies the process. Then you get down to the question of cost which is a much simpler determination. That is made by CPAs and MBAs, and you let those people who have the skills and the training in the medical side do it.

I am not trying to just build a case for the FDA, but it seems that we may be reinventing the wheel here. I am going to go up and testify in a little while—and I think I may be the only one there at appropriations asking to get some more money for HCFA—but I don't think you are going to get any. I have been advised that by some of my distinguished colleagues from the other side of the aisle. So, I am going to go up and go through the motions, but don't bet the farm on how much money I am going to bring back for you.

Mr. HASH. We wish you well, Mr. Stark.

Mr. STARK. Yes, thanks. I am concerned that you may be building an unnecessary bureaucracy here in making medical decisions when really I look at Medicare as a bill-paying operation and not as a determinant factor in what kind of medical procedures are useful. That is my worry. We could do it faster, and, besides which, you don't have the people to do it anyway, it seems to me.

Dr. KANG. If I may, first of all, I just want to say at the outset, we are not interested in duplicating what FDA does and to the extent that information is generated in their processes that help us make our coverage decisions, we will use every single piece of information. There is an important difference, though, in terms from a medical science standpoint of what FDA does versus what we need to do as an insurer. FDA looks at the safety, we do care about that. If they judge it safe, we will say it is safe. They care also about what is called efficacy, which means does the product or device do what it says it does? What we care about as a payer, though, is whether it is going to improve the ultimate outcome for the beneficiary, that is one issue. The second is does it do a better job than what we are currently covering? As a steward of the Medicare Program, if it does not do a better job of things than what we are currently covering, I think I would be back here next year explaining why. That is an issue that the FDA, in its trials, does not really look at. It only looks at the device or technology from its individual perspective.

Mr. STARK. All right, but, on a marginal cost basis, Doctor, isn't it easier for FDA to expand their tests? They have already got the personnel with the scientific and technical training to make that next step. Why not ask them, contract out to them—you guys contract out 90 percent of what you do anyway—why not contract out to FDA and say, "Hey, next time you do this, go the next step, and give us a comparison," which is often done by the New England Journal of Medicine? I suppose you could take them, but they are not a governmental agency. Or, you could even choose the specialty groups. I have no quarrel with that, if the American college of whatever they are decide that they, in their wisdom, make this decision, maybe HCFA could take that.

I am just saying that I don't think you have got nearly the personnel to do it, and I don't think there is much realistic chance that we are going to give you the money to do it. Therefore, how about using resources that might be available?

Mr. HASH. Well, let me just respond quickly, Mr. Stark, by saying I think we would be open to discussing ways of getting the job done. I do want to go back to a point that you made which was you kind of look at us as a bill-paying organization. We actually see

ourselves as having a much broader role. In addition to our fiduciary responsibilities, we are responsible, under the statute, for many standards of quality in the health care delivery system on behalf of our beneficiaries. So, our responsibilities encompass much more than just paying correctly. It is making sure that we are paying providers who meet appropriate standards; that, in fact, we are meeting our responsibilities as a quality purchaser as well as a——

Mr. STARK. Well, now wait a minute. Mike, you mean, deeming JCAHO is discharging a responsibility? To let Columbia Hospital who is on the JCAHO Board decide whether Columbia Hospital is providing quality care. You are going to look at me with a straight face and say you are doing anything to protect the health of the beneficiaries? You subcontract that out to very suspect people, I might add, in many cases. So——

Mr. HASH. Under the statute, as you know, Mr. Stark, we are required to utilize the services of those agencies. But where we have discretion, we have been imposing our standards directly.

Chairman THOMAS. Thank the gentleman; that was from a friend. [Laughter.]

Does the gentlewoman from Connecticut, also a friend, wish to inquire?

Mrs. JOHNSON of Connecticut. Breathtaking. [Laughter.]

Breathtaking hypocrisy. I am simply—I am also speechless but not quite. [Laughter.]

I don't know whether to cry in frustration or demonstrate in rage, but I can tell you if I were a senior citizen in this country, I would be out there demonstrating, and I don't know why people aren't. The Department of Labor just issued a proposed regulation: all private plans, fee-for-service or managed care, 15-days appeals process.

The administration, with much fanfare, much fanfare—I mean, that is probably what galls me here is the hypocrisy—much fanfare announced that the recommendation of their Quality Commission had been implemented in every Federal program, and the Congresswomens' Caucus held a hearing, and I was one of the Chairs, and we heard testimony from everybody saying, "Oh, yes, we have implemented all those appeals processes." And then in preparation for this hearing, to learn that under part A administrative law judge appeals average 301 days; part B appeals average 425 days. This is not justice; it doesn't reflect what has been said, I know not by you guys, and it is hard, because I know you are out there trying to fix things, and you are slugging through the details.

What do you think the private sector is doing? Don't you think the private sector is struggling with how to improve outcomes? Whether something should be covered because it is quality or not quality? Of course they are. They are struggling with costs and quality too, but the shear, breathtaking hypocrisy of what this administration has said in the last few years about the appeals process and they are providing under Medicare and then what we learn in preparation for this hearing blows my mind. And I hope everybody here hears it, because, by gum, Medicare has got to change.

But my question to you goes to the overturn rate. Now, one of the big discussions we had in the patient bill of rights and one of the things I accomplished in the Republican proposal was that the

overturn rate of appeals ought to be right out there on the first page—big, bold—any plan ought to be accountable for its overturn rate.

Last year, the administrative law judge reversed 50 percent of the part B decisions and 72 percent of the part A decisions, the fiscal intermediary decisions. I mean, that is appalling; that is really appalling. Any private plan out there would be so blasted, they wouldn't have anyone sign up for 100 years. I really think, with all due respect, and I understand that you are working on this, and I am glad you are making progress, but I think everybody on the other side of the government who has gotten out there and pretended that Medicare recipients are well protected; that they have any voice at all, actually, in challenging whether a care decision is fair or not fair or appropriate or not appropriate—I will tell you, preparing for this hearing has blown away any belief I ever had that seniors had any voice or any protection when they think that they have been disadvantaged.

So, I would just like you to direct your attention—you can't satisfy all my outrage, because it goes back to statements made by the President, by the Secretary of Health and Human Services, by other leading people taking responsibility for accomplishing things they clearly did not accomplish and castigating people like me for not being tough enough. I thought 60 days wasn't tough enough, and you guys are up there in the hundreds and hundreds and hundreds of days. So, I want you to address yourself not to my rage about the fact that there has been no system there and that seniors have had no voice but to how you explain the overturn rate and what you are going to do about it?

Mr. HASH. I would be happy to, Mrs. Johnson. The overturn rate, I think, is largely a function—it goes back to what we were talking about earlier—of local medical review policies being about 90 percent of coverage and 10 percent national coverage policy under Medicare. The administrative law judges—and this is not well understood—are not bound by local medical review policies. So, they may, in effect, establish Medicare policy, not make a judgment about whether existing policy has been applied appropriately. That means they have the discretion that other reviewers do not have who are bound by local and national Medicare coverage policies. The decisions that are made by our contractors before cases go to administrative law judges are limited to the local review policies. When they get to the administrative law judge level, there is no such limitation.

And, last, in terms of the backlog, which is outrageous—and I share your concern about it, and it does not give people timely results in the appeals process; no argument about that—that is why in our testimony today we have been talking about the steps we have been taking with the Social Security Administration to make sure that we have an adequate cadre of administrative law judges which are at SSA and that they have been trained in the Medicare Program and understand our policies, and we have asked for additional money in order to support a larger ALJ process. That it is, I think——

Mrs. JOHNSON of Connecticut. I will just say, given the statistics, I don't think your recommendations are adequate. This is a system

that doesn't communicate with itself, and, therefore, cannot deliver on timely or fair decisions and makes decisions that are apparently being made at the local level look like fraud. So, there was a lot of analogies throughout this system, but either your policies are real or they aren't, and they either have standing or they don't. So, I think you have to go a lot further if you are going to end up with some statistics that are decent, that are respectful, and that give our seniors confidence in the system. Thank you. Thank you, Mr. Chairman.

Chairman THOMAS. Thank the gentlewoman. Does the gentleman from Washington wish to inquire?

Mr. MCDERMOTT. Mr. Chairman, I sometimes have been critical of the process here, but I really think your having this hearing on one of the toughest issues—is really very important, and I think that——

Chairman THOMAS. Well, just let me tell the gentleman that I am pleased that at least the notice came out the same day of the hearing so that we have in front of us what HCFA proposes instead of speculation on what it is. So, in that sense, it might be even more useful than I had anticipated, because I was trying—so at least we have real product, and that will be useful.

Mr. MCDERMOTT. I think that, with all due respect to some of the criticism here, I was a claims examiner for three or four health and welfare trusts for a labor union, so I have sat and struggled with the problems, so I have a little bit more hands on experience, perhaps, than some, and I think that before we get too hard on the people sitting out here, I think we have to look at the budget which freezes HCFA's administrative budget for the next 10 years. I think if we are going to deal with these, we have to at least put that in the mix.

But let me just give you an example, because I would like to hear how you deal with this. I had a colleague who retired from the Foreign Service and went into the Blue Cross Blue Shield of Washington, DC. His wife had uterine cancer and, long story short, a stem cell transplant was recommended, and they denied it. So, he called me and he was an oncologist and so knew what was what. I made calls, got put on hold, finally had to use my congressional title to get to somebody who would tell me that there was a committee, that they couldn't tell me when it met, of professionals from all over the country who made this kind of decision. I discovered that when he left Washington, DC, if he had transferred to Blue Cross Blue Shield of Washington in Alaska, the treatment would have been covered. So, even in the BlueCross system there are these problems.

So, what I would like to understand is when one of these issues comes, how does it get dealt with so that you don't have—I mean, maybe the local issues are always going to be there—but how does the national policy get set? How do you take—I don't know what it is, stem cell transplant, because it is sort of cutting edge with bone marrow transplant these days; you are getting it everywhere. You had a big case in California, and these cases are all over the place. How does that get dealt with inside?

Dr. KANG. I think that and this takes us back to the regional premise of the Medicare Program—many new technologies develop

locally. So, for example, with stem cell transplant, there may be a great center in California.

Mr. MCDERMOTT. Or in Seattle.

Dr. KANG. Or in Seattle. So, the local carriers, based on the local practice of medicine, decide to cover it there. That then allows some clinical information to be derived which then, at some point, could lead to a national coverage decision for the entire country. And this is the balancing act that we are trying to preserve. That there are places where we do need national decisions; where the variation is unacceptable, either under or overutilization. There are places where we want local flexibility for technologies to be created, developed, and diffused.

Mr. MCDERMOTT. Does the problem, then, develop because there is a report in the press or something about the use of a particular treatment that then gets somebody to come in another area of the country saying, "Why aren't you doing this?" And then it is brought and it is denied, because it is not in local practice? Is that what——

Dr. KANG. If it comes to our attention and the evidence exists, we will then cover it at the national level.

Mr. MCDERMOTT. But the first denial will occur at the local level. There will be a whole bunch of denials in some areas if they are not doing that.

Dr. KANG. The one other thing I should note is that the beneficiary is covered in the area that the service is delivered not where the beneficiary lives. So, I should say that there is some relief here to the extent that if some beneficiary in New York is really interested, they could go over to Seattle to get it. That is in the Medicare Program.

Mr. MCDERMOTT. And the denials at the local level are of things that have not filtered—is there a process by which you say "We have had enough complaints on this issue; we received 5,000 complaints on *X*. Let us take it to the national level and make a decision?" How do you sort through that at the local level? It seems to me you could sort through a lot of those local decisions by having a trigger that would suddenly send it up to the top where you said "This is what we are going to do."

Dr. KANG. And we are looking into that. That is an issue in our relationship to the administrative law judges, and I think there should be a trigger. We are pursuing a kind of a warning signal where we really need to revisit this at the national level.

Mr. MCDERMOTT. It seems to me you can weed out a lot of those whatever how many thousand complaints there were that Mrs. Johnson is worried about, which I worry about. If you have something pressing and you have got a pain or an ache or whatever and it takes 301 days to find out whether you can have the treatment of not, it sounds like the British system of waiting in line to me.

Mr. HASH. If I may, Mr. McDermott——

Chairman THOMAS. Sounds like national health care to me.

Mr. HASH. If I may——

Mr. MCDERMOTT. That happens in insurance companies, though, so let us not throw rocks at each other. Go ahead.

Chairman THOMAS. That wasn't a rock.

Mr. HASH. In many cases, in the traditional fee-for-service Medicare Program, as we have been talking about here, a service will

be, in fact, provided, and then the issue about whether it is going to be paid for is adjudicated through this process that may involve an ALJ. But the important issue is that in many cases the service has already been rendered.

Mr. MCDERMOTT. And then who gets stuck with—is it the provider who gets stuck or the beneficiary who gets stuck?

Mr. HASH. It depends, because in the statute there is a provision called the limitation on liability and it sets forth the rules for determining whether or not a provider or a beneficiary should be held liable for something that turns out not to be covered. If the provider and the beneficiary did not have reason to know that something would not be covered, they are not held liable financially for that. In the case of the provider, they can be paid, and in the case of the beneficiary, if they have already paid, they are due a refund.

Mr. MCDERMOTT. So, if they have—but if it is denied at—what happens to the denial? The denial is just wiped out by the fact they had no reason to know? Or there would be no denial, I guess.

Mr. HASH. The service has—in the case I was giving you—already been provided. If there is a denial of payment for it, there is a limitation on the liability under those circumstances. That is also the vehicle through which people are put on notice that a given procedure or service is not covered, because now there has been notice given that it isn't, and that is the reason for the limitation on liability provisions in the statute.

Mr. MCDERMOTT. Thank you, Mr. Chairman, for giving me that extra time.

Chairman THOMAS. Thank you. The gentleman from Washington, as part of our aside, said that "Well, those kinds of delays and so on occur in insurance companies as well." If an insurance company—just pick one—say, AETNA consults with the Advisory Commission, and they come to the conclusion that something shouldn't be covered, can that decision of noncoverage be contested in court?

Mr. HASH. I would assume it could be pursued under State law——

Chairman THOMAS. Well, they just got hit with a $120 million judgment because they didn't cover a procedure, and yet seniors aren't able to appeal or sue HCFA if they disagree with a national coverage decision. So, I find it somewhat interesting that someone can wind up going to court, being sued and lose if they deny a coverage but that process that you are advocating that we adopt does not even allow a senior to disagree with a national coverage decision and have a remedy in terms of going to court.

Mr. HASH. It would, actually, Mr. Chairman. The procedure that outlined in today's notice does, in fact, provide that any party, including a beneficiary, would have the opportunity to ask for reconsideration of the national coverage policy.

Chairman THOMAS. I believe I said go to court. Can they go to court, ultimately?

Mr. HASH. A Medicare beneficiary?

Chairman THOMAS. On a decision of the Medicare Advisory Commission.

Mr. HASH. The Medicare Advisory Commission, Mr. Chairman, is not a decisionmaking body.

Chairman THOMAS. Right, and if HCFA denies it—and if HCFA denies it?

Mr. HASH. They can request a reconsideration. If that reconsideration is denied, they also can appeal any denied claims through the appeals process. The last step in that process is judicial review.

Chairman THOMAS. Does the gentleman from Louisiana wish to inquire?

Mr. MCCRERY. Yes. In fact, I want to follow up on the Chairman's questioning. It is true that if a beneficiary appeals a decision by a fiscal intermediary and the PRO and so forth, but then he goes to the ALJ and still doesn't like it, he can appeal it to HHS, and then if he still doesn't like it, he can go to district court.

Mr. HASH. Correct.

Mr. MCCRERY. The U.S. District Court. And what is his remedy if he wins in district court?

Mr. HASH. Well, the remedy, presumably, would be to restore the coverage that they had sought and would be awarded to them as a result of the court order, the court decision.

Mr. MCCRERY. So, his remedy, if he wins in district court, after expending all this time and energy going through the appeals process, is that he gets the benefit. That is the extent of his remedy?

Mr. HASH. The remedy would be—of course, presumably, the individual would have already gotten the service—that any liability they might have would be satisfied by the court judgment.

Mr. MCCRERY. What do you mean by a liability?

Mr. HASH. The cost of the care that they sought and received.

Mr. MCCRERY. So, the extent of a liability in district court is the cost of covering the benefit?

Mr. HASH. I understand your question, and I am not really sure I have the correct answer. I would be happy to answer it for the record. I am not an attorney and I am not sufficiently familiar with what the scope of remedies that the U.S. District Court might——

Mr. MCCRERY. Well, let me ask it another way. If the beneficiary prevails in the U.S. District Court, can he receive in a judgment collateral damages—pain and suffering, mental anguish, general damages—associated with denial of the benefit?

Mr. HASH. I would like to answer for the record; I just do not know, Mr. McCrery.

Mr. MCCRERY. Is there anyone here from HCFA that knows the answer to that?

Mr. HASH. I don't think so. I would like to consult with our general counsel, and I would be happy to provide an answer for the record.

[The following was subsequently received:]

A beneficiary or a provider is only entitled to payment for the item or service in question if they receive a favorable decision at the U.S. District Court level. There is no statutory provision that authorizes payment for pain and suffering, general damages, or interest on the amount in question. In certain circumstances, a beneficiary may be entitled to reimbursement for certain legal fees under the Equal Access to Justice Act. The beneficiary would have to meet the requirements of that statute to qualify.

Chairman THOMAS. Will the gentleman yield?

Mr. MCCRERY. Well, being a lawyer, I can give you my opinion. My opinion is that you cannot in district court recover anything other than the cost of the benefit that was denied which is the current law also for ERISA plans that are the subject of so-called patient protection bills floating through the Congress and endorsed by the administration. So, since the administration seems to want to impose on the private sector the ability to be sued in not only the U.S. District Court but in State courts and receive judgments that would provide damages other than the cost of the benefit. Is the administration endorsing a change in public policy to allow Medicare beneficiaries to sue in State or U.S. district courts for damages as well?

Mr. HASH. Mr. McCrery, the administration's recommendations are, in so far as I know, consistent with what is in the statute now for the remedies that Medicare beneficiaries. We have not proposed a change in remedies for Medicare beneficiaries that are currently either in regulation or in the statute.

Mr. MCCRERY. OK.

Chairman THOMAS. On that point, would the gentleman, without any penalty on his time, yield to me?

Mr. MCCRERY. Sure.

Chairman THOMAS. I am looking at a section of the law which was put in in OBRA 1986, the Omnibus Budget and Reconciliation Act of 1986. Mr. Hash, were you up on the Hill in 1986?

Mr. HASH. I was not, Mr. Chairman.

Chairman THOMAS. You were not. What I am looking at is a statement of review of any national coverage determination under section 1862(a)(1) respecting whether or not a particular type or class of item or services is covered under this title shall be subjected to the following limitations: a, such a determination shall not be reviewed by the administrative law judge, right?

Mr. HASH. That is a noncovered service, excluded service?

Chairman THOMAS. Yes.

Mr. HASH. Right.

Chairman THOMAS. Such a determination shall not be held unlawful or set aside on the grounds that a requirement in section 553 of title V of the U.S. Code to section 1871 be relating to publication in the *Federal Register* notification, and sort of thing or, c, in any case in which a court determines that the record is incomplete or otherwise lacks adequate information to support the validity of the determination, it shall remand the matter to the Secretary for additional proceedings to supplement the record, and the court may not determine that an item or service is covered except upon the review of the supplemented record.

Do you have any indication of how many cases the court determines that the record is incomplete or otherwise lacks adequate information? My assumption is that may even be the majority of them. Is it rare?

Dr. KANG. I am aware of only one.

Chairman THOMAS. Of only one.

Dr. KANG. And we are actively reconsidering it on the basis of scientific information.

Chairman THOMAS. And what year are you into the reconsideration? This is the second or the third year?

Dr. KANG. This would be—I think we are in the first year. I can get back a more specific time for the record, but I am only aware of one.

[The following was subsequently received:]

Approximately 2 years ago, a district court remanded a case involving electrical stimulation for wound care for further development of the record. We are examining additional materials and will supplement the record with our findings.

Chairman THOMAS. OK. The gentleman from Louisiana.

Mr. MCCRERY. Thank you, Mr. Chairman. I only have one other observation to make and that the gentleman from Washington pointed out that because of budget constraints, HCFA may not be able to do as much as they would like to in the area of appeals and expediting those appeals, and it is good to know the gentleman recognizes that such processes cost money, and when we impose those processes on the private sector, we should recognize that we are passing on a cost to those private sector entities that they must then pass through to beneficiaries, their policyholders. So, I thought that was also a good point.

Mrs. JOHNSON of Connecticut. May I?

Chairman THOMAS. It is your option. Your Mr. Nice Guy record would be at stake, though. The gentlewoman from Connecticut—I am holding for the gentlewoman from Florida, and she said she was going to come right back, so——

Mr. MCDERMOTT. Mr. Chairman, if I could respond, because I think this is an issue where we have—this is a public policy issue that is a very tough one, how you give patients the right to look at and appeal what has been decided, whether it be by the Federal Government or by the private industry. And I think that it is probably equally confusing on both sides and costly on both sides, but I think that maybe we would do the country a service if we decided on a universal policy on how you could appeal applying both to the Federal Government and to the private sector. I mean, a patient whether they are covered by a private sector HMO ought to have the same rights as the person who is covered by the fee-for-service under HCFA, in my view.

Chairman THOMAS. Tell the gentleman that was part of my opening statement in which I found it ironic that you folks were criticizing our H.R. 4250 in terms of the failure to move judiciously to the judicial review, and when I began looking at HCFA, I found out that the morass there was far worse and that this may be an area that you and I can agree on; I will reexamine it carefully. [Laughter.]

Mr. MCDERMOTT. If I agree with you, you know you must have missed something.

Chairman THOMAS. In which—no, no, because I do not understand the logic, and, frankly, I apply it to the payment of bills, late fees, and everything else how government gets to follow rules that the private sector doesn't get to follow when it is the individuals desire to make a change. I think if, in fact, based upon the statement that the gentlewoman from Connecticut indicated, if we want

to impose a 15-day review process on HCFA, I am all for that, but I don't think that is what the gentleman meant.

Mr. MCDERMOTT. I think the problem or at least what I heard when you were asking before about the FDA, it is like around Congress where we have the authorizers who authorize stuff and then the appropriator has got to find the money to do it. We authorize a whole bunch of stuff around here that we never do, and these guys, in my view, are like the appropriators in the sense that the FDA can authorize something which may have only minimal value or whatever, but then HCFA has to decide where do we get the money to pay for it? And that is where we control how much they can do of all that.

Chairman THOMAS. I will tell the gentleman from Washington, I am even now more concerned, because, as I recall, it was my colleague from California, Mr. Stark, who was making the FDA inquiries rather than this gentleman from California.

Mr. MCDERMOTT. I am sorry. We would never do that.

Chairman THOMAS. Any additional comments? The gentlewoman from Connecticut.

Mrs. JOHNSON of Connecticut. Yes, thank you, and I would like nothing more than to have a consistent, comprehensive policy for public and private patients. I think the source of my absolute outrage and my passion of anger is the injustice of the current system and the shear hypocrisy with which the political process is dealing with it, and I think we have got to get beyond that and be honest. There are good reasons why we don't want to allow your national decisions to be appealed, but those might be the same good reasons why private sector plans who also struggle with cost and delivery of service want some similar protections. We just have to be honest and consistent, and we aren't, and the politics around Medicare have really driven the debate to where it is hardly recognizable as related to reality, and I think this claims process hearing that we are having now demonstrates that.

But, I just want to ask you one thing: Do your new regulations make it absolutely clear that HCFA is bound by administrative law judge decisions?

Mr. HASH. No, ma'am, they do not, because administrative law judge decisions actually apply to the case that they have decided and reviewed. They are not applicable to the program at large. That would be like establishing coverage policy decisionmaking by administrative law judges.

Mrs. JOHNSON of Connecticut. Wait a minute, wait a minute now. We are an agency that took a whole year, but, finally, they got an administrative law judge decision that HCFA should allow them to resubmit complaints. We have not been able to get compliance with that decision. When you go at an agency at their own expense, goes all that way and time. This is an agency, as home health agencies are, sinking in the mud of bankruptcy. We finally get a decision from the administrative law judge, and there is no requirement in the law for them to comply by it or else that is the way they act. Now, in your regulations, does it make it clear that if a HCFA decision is appealed to an administrative law judge in accordance with your regulation, that just as the contractor has to comply, HCFA has to comply?

Mr. HASH. I believe that if a case is decided, a specific case, when it is decided in favor of the plaintiff by an administrative law judge, for that plaintiff the decision is binding.

Mrs. JOHNSON of Connecticut. Well, we need to have that very clear in the regulations, because that isn't what is happening in real life.

Mr. HASH. We need to—I would like to talk to you——

Mrs. JOHNSON of Connecticut. And I will give you this case, so that you will see it, because we cannot have citizens going through this lengthy, costly process and then agencies simply saying "No, we are not going to do it," and that is what they said.

Mr. HASH. We need to—I need to look into it. I would be happy to——

Mrs. JOHNSON of Connecticut. Thank you. We will contact you, Mr. Hash. I appreciate that you are trying to reform the system, thank you.

Mr. HASH. Thank you.

Chairman THOMAS. I want to thank you folks very much. I do appreciate the effort that you have made to correct the fact you weren't in compliance with the law, and we will review your offering. Obviously, a number of people will begin reading the notice, and we will get back to you; I appreciate it. Thank you very much.

Mr. HASH. Thank you, Mr. Chairman.

[The following questions were submitted by Mr. Ramstad. The responses of Mr. Hash and Dr. Kang follow:]

1. I greatly appreciate your recognition for the need for timeframes by including them in the recently published Notice. Can you tell me, however, what you consider the starting points for these time frames and approximately how often you expect to meet them?

A formal request for a national coverage decision must be in writing and include supporting documentation as spelled out in the April 27, 1999 Federal Register notice. Acceptance of a formal request will begin a 90 calendar day clock for us to respond to the requestor in writing. Our response will also be posted to the Health Care Financing Administration's (HCFA) home page on the world wide web. Our written response to a formal request will include, at a minimum, one of the following:

- A request for supporting documentation if additional information is needed. We will identify, in writing, the information that we require to enable us to review the request. A resubmission of the revised formal request triggers a new 90 day calendar response clock.
- A decision that the request duplicates another pending request and we will combine the requests and respond with a single decision.
- A decision that the request duplicates an earlier request for which we have already made a national coverage decisions (and that there is insufficient new evidence to being the process again).
- A referral for a technology assessment. We will make every effort to assure that we obtain timely assessments.
- A referral to the Medicare Coverage Advisory Committee for consideration. We will make every effort to assure that we obtain timely consideration.
- A national noncoverage decision (which precludes contractors from making Medicare payment).
- No national coverage decision (which allows for local contractor discretion).
- A national coverage decision with limitations on coverage.
- A national coverage decision without limitations on coverage.

In general, we expect to meet our self-imposed timeframes. However, certain circumstances may prevent us from meeting the timeframes such as the submission of additional information by the requestor or materially significant information submitted by others. Any related changes will be formally communicated to the requestor in writing and posted to the HCFA home page on the world wide web.

2. Minnesota's Medical Alley has talked to you a great deal about early collaborative meetings between industry and HCFA at which a written, mutual agreement may be reached on the specific information HCFA requires to make a coverage determination. I noticed they are not included in the Notice, and I must tell you I am disappointed about the absence of this reasonable and sensible request.
Currently, stakeholders act upon advice given to them in the informal early meetings, but HCFA often dismisses the studies later as falling short of providing the necessary data. For some coverage decisions, this has led to a continuous circle of studies and "not yet" decisions. I know of a few Minnesota companies that have experienced this "run around" for years. Is there any assurance this will not continue under the new process?

We do not believe this will occur. The April 27, 1999 *Federal Register* notice makes our coverage determination process open, understandable and predictable. The notice is explicit on the types of information that must be included in a formal request for coverage determination. Later this year, we will complete this process by publishing a proposed rule for comment on the criteria we use to evaluate whether an item or service meets the statutory requirement that items or services be "reasonable" and "necessary."

Individuals and organizations, however, may still contact us informally. Informal discussions can include assistance to the requestor to clarify the amount and kind of information necessary for a coverage determination. We are drawing a distinction between the formal and informal requests and, while we will be as helpful as possible through informal discussions, only formal requests will generate an official response in the timeframes established in the April notice.

I have been told that someone at HCFA said the Agency "doesn't have the expertise to design the studies." If HCFA doesn't have the expertise to say what studies could or couldn't provide enough information and to make the final decision, then does HCFA make the final coverage decisions?

In making national coverage decisions, HCFA decides whether items and services are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member. These decisions are usually based on medical and scientific research and data that demonstrate whether the item or service is useful for a particular condition. Currently, many companies hire consultants who design these scientific studies and HCFA is often provided a copy of the results of the study. We would be concerned about any proposal that would give HCFA a role in designing a scientific study that would appear to guarantee a particular coverage result without considering intervening changes in health care science and technology. Further, participation in a study's design does not guarantee that the study results will adequately demonstrate that a treatment is reasonable and necessary.

We do, however, utilize biostaticians and clinical experts on an as needed basis to help us review medical and clinical information that is submitted to us to determine whether it demonstrates that a therapy is reasonable and necessary. In addition, we will refer formal requests, as needed, to the Medicare Coverage Advisory Committee to make recommendations to us about whether services can be considered reasonable and necessary. The members of the advisory committee will be selected from among authorities in clinical and administrative medicine; biologic and physical sciences; public health administration; health care data and information, management, and analysis; health care economics; medical ethics; and other related professions.

The only sensible reason I can understand for your opposition would be that it is an issue of resources. If it is an issue of resources, please tell me exactly how it is a resource problem given the 15–20 national decisions made each year. If you give me specifics on how many people you need and what particular jobs the would do, I can try to help.

We anticipate that there will be an increased workload for HCFA staff who work in the coverage area and we have dedicated additional resources. We have hired new personnel including a former FDA executive secretariat who was responsible for running an advisory committee panel there. If the formal requests we receive are complete, the staff that we currently have or are in the process of hiring should be able to handle the requests according to the timelines outlined in the coverage notice. However, if a significant percentage of the formal requests are incomplete, we will face resource constraints. Incomplete and informal requests place the burden on the agency to outline what is necessary for the request to be accepted. We

believe, though, that the requirements for the formal requests established in the notice are clear and should minimize the number of incomplete requests.

3. Can you explain the legal and practical distinctions between publication of the coverage process policy as a rule versus publication as a notice? Is the agency legally bound by the provisions in the notice?

The Administrative Procedure Act enables (APA) an agency to issue "rules of agency organization, procedure, or practice" without completing notice and comment rulemaking (5 U.S.C. §553(b)(3)(A)). The legal effect of these rules, however, is not identical to legislative rules adopted through notice and comment rulemaking.

In contrast to legislative rules, rules of agency organization, procedure, or practice may not impose new substantive legal requirements. The primary purpose of the procedural rules exemption in the APA is to ensure that agencies retain latitude in organizing their internal operations. Procedural rules express the agency's intended course of action, but do not conclusively affect the rights of private parties.

While the agency is expected to follow the procedural rules it has put in place in order to make decisions—and we certainly intend to follow the procedures that we have developed for issuing national coverage decisions—the agency may amend those procedures without completing the notice and comment procedures. In addition, the agency is not required to provide a 30 day delayed effective date as is normally required for a legislative rule. HCFA will, however, provide advance public notice before making any changes to the procedures announced in the April 27, 1999 notice. This practice is consistent with 5 U.S.C. §552(a)(1)(C).

4. How will you consider, respond to, and incorporate public comment on that notice? Do you intend to meet further on the notice with stakeholders and modify the notice to reflect relevant information learned in comments from such meetings?

We welcome comments from the public on the processes spelled out in the notice. Comments may be submitted to us in writing or via the HCFA homepage. The appropriate addresses are included in the April 27, 1999 notice. We will consider these comments, respond if necessary, and incorporate as appropriate.

5. How does the current local decision-making process increase patient access to medical technology?

Where no national policy exists, our local contractors develop policy as they identify a need. This may in some cases provide access to new technologies before national policy is established. Our goal, however, is to provide more timely and consistent national policy to improve access to new technologies as quickly as is warranted by medical and scientific evidence for all beneficiaries regardless of where they live.

Chairman THOMAS. Could I then ask the second panel to come forward?

Mr. MCDERMOTT. Mr. Chairman. I would like to apologize. I really would like to stay for this, but NATO has made the airports crazed, and so some of us have to get going to get planes to go home. So, I am sorry I can't stay.

Chairman THOMAS. Well, I am sorry, too, and that is OK, because this really is a panel of folks who are highly regarded especially in terms of representing the interests of beneficiaries. The first witness is Professor Eleanor Kinney of Indiana University, and she is a former official at the Department of Health and Human Services, serving in both Democratic and Republican administrations; probably the leading national scholar on the issue.

Terry Coleman, who has been Deputy Administrator of HCFA, Chief Counsel of HCFA, both at the Food and Drug Administration, and Health and Human Services.

And, last but not least, Vicki Gottlich, who has as an attorney been representing the National Senior Citizens Law Center, and I am a little worried about testing cause and effect, because I believe

the last time you were supposed to testify at this hearing an alarm went off, a fire alarm, and we were not able to have the rest of the hearing. So, it is with some trepidation I welcome you for a second try.

And, with that, Ms. Kinney, if you would begin, and I would indicate that all of you who have written testimony, it would be made a part of the record, and you can address this in any way you see fit in the time that you have.

Professor Kinney.

STATEMENT OF ELEANOR D. KINNEY, J.D., M.P.H., PROFESSOR OF LAW; AND CODIRECTOR, CENTER FOR LAW AND HEALTH, INDIANA UNIVERSITY SCHOOL OF LAW, INDIANAPOLIS, INDIANA

Ms. KINNEY. Thank you very much, Chairman Thomas. I am very honored to be here. I would like to offer my testimony for the record and just touch on a few points in my remarks that I think might help clarify some of the issues before you today.

In my judgment, this is a very complicated and difficult issue. There are a lot of interests at stake. Specifically, there are four stakeholders that I think have very important interests that are not always consistent with one another—first, beneficiaries, of course, being the most important; second, HCFA; third, the medical profession with an interest in practice; and, fourth, a very vibrant device in technology industry that is important to our economy in many respects.

In my judgment, the current controversy is driven by four factors, again, that often work at cross purposes. These factors make it difficult to develop national coverage policy at the national level and also at the local level by Medicare's contractors. Specifically more and more services are going to the part B side, which puts greater financial pressure on the part B program. Incredible advances in medical technology are increasing at a great pace. There's continuing inflation in Medicare Program expenditures, of which I think you are acutely aware. Finally, the numbers of Medicare beneficiaries will be increasing in the future, which make even decisions on small, little-ticket items potentially very, very expensive for the Federal Government and taxpayers.

I was pleased to see that these hearings address both national coverage policy, local coverage policy, and the beneficiary appeals process, because they are inextricably entwined and not in a particularly healthy way.

Our major problem has been with the way HCFA makes coverage policy both at the national and local level. I have not had an opportunity to look at the coverage policymaking procedure that was proposed today. I hope they have dealt with the three major problems that I see with HCFA's coverage policymaking process in the past: a process that is closed, a process that is duplicative in some respects of the FDA process, and a process that did not permit interested parties to participate in a meaningful manner. I have heard good things about the new process that HCFA has proposed. Although I haven't studied it, it sounds like some important reforms have been and hopefully will be achieved. The opening up of the national coverage making process is the essential step.

From what I have heard today and previously, I think we need to give greater attention to policymaking at the local level. At least we must make the policymaking process at the local level consistent with what is done at the national level. If HCFA has made a national coverage determination, providers and beneficiaries and the industry should be able to expect that the national policy will be enforced at the local level.

We have talked a lot about problems with beneficiary appeals. The delay in these appeal procedures is unforgivable. Further, the multiple layers which often don't seem to have a readily apparent purpose, seem cumbersome. However, the real problem with the part B appeals process is that it is now the battleground where disputes over coverage policy are being fought, and it is an inappropriate battleground.

There are two types of issues that come before the part B appeals process that need attention. The first is special situations in which the beneficiary might really benefit from a noncovered item where conventional, covered treatment modalities have failed. Ideally, Medicare should be able to tailor a treatment process for such a beneficiary in extraordinary circumstances and manage the use of noncovered items or services in such cases through case management. That is a little bit different than we are talking about today, but I think that our process doesn't really address this need of many beneficiaries. With the second issue, we simply have a process that—well, I see that the light is on telling me that I ought to come to close——

Chairman THOMAS. No, no, no, that is the yellow. Here in Washington, you have another 4 minutes to drive the intersection. [Laughter.]

Ms. KINNEY. Oh, OK. Out in the hinterlands, we get worried when we see yellow.

At any rate, the second problem with the part B appeals process is that it is handling the dispute that device manufacturers have with HCFA's policy decisions implicit in national coverage determinations. The part B appeals process should not be handling these issues and adjudicating what is appropriate national coverage policy for the Medicare Program. The current law in Social Security Act section 1869 is correct. Having said this, I want to emphasize that HCFA must operate a policymaking process for national coverage policy where all the players are able to put their best medical evidence on the table and get a decision that they believe is credible. That has not been done to date.

HCFA can't have it both ways. It is unfair to block considerations by the ALJ, which is appropriate in my judgment; and to require that courts remand national coverage policy to HCFA for amplification of the record before invalidating which is, again, probably appropriate, and then run a private policymaking process for making national coverage policy. HCFA needs to open up that policymaking process and let everybody come in, make their views known, and put their best evidence before the policy decisionmakers. In my judgment, if you operate the initial policy process correctly, you are more likely to avoid the kinds of appeals that shouldn't be before the part B appeals process in the first place and get better decisions all around for the protection of beneficiaries.

[The prepared statement follows:]

Statement of Eleanor D. Kinney, J.D., M.P.H., Professor of Law; and Codirector, Center for Law and Health, Indiana University School of Law, Indianapolis, Indiana

It is an honor to appear before the Subcommittee on Health of the House Committee on Ways and Means to provide testimony on Medicare Coverage Policy Decisions and Beneficiary Appeals. In my testimony today, I would like to present some observations about the processes for making and implementing Medicare coverage policy and also the procedures available for beneficiaries and their assignees to appeal the adverse claim denials based on both national and local Medicare coverage policy.

BACKGROUND ON THE MEDICARE PROGRAM

Medicare is a federal program providing comprehensive health insurance for the elderly, severely disabled and people with End Stage Renal Disease. Medicare is the nation's largest health insurance program and covers 37 million Americans.

Traditional fee-for-service Medicare is comprised of two programs—the Hospital Insurance program (Part A) and Supplementary Medical Insurance program (Part B). Part A covers hospital care and related home health and skilled nursing home care. Part B covers physician and other outpatient services. Under the fee-for-service program, Medicare beneficiaries obtain services directly from the providers they select. Medicare pays Part A providers directly under various payment methodologies. Assuming that the beneficiary assigns his or her claim for Part B benefits directly to the physician, supplier or other provider, Medicare pays the provider or supplier directly for the services.

In the Balanced Budget Act of 1997, Congress enacted a new "Part C" of the Medicare program—the Medicare+Choice program. As of January 1, 1999, Medicare beneficiaries have the option of enrolling in Medicare+Choice plans. Medicare beneficiaries must select a Medicare+Choice plan or enroll in the traditional Medicare fee-for-service program under Parts A and B described above. Medicare+Choice plans must provide the array of benefits in Parts A and B but may offer additional benefits with savings achieved in efficient delivery of services to Medicare Beneficiaries.

BENEFITS AND COVERAGE UNDER THE MEDICARE PROGRAM

Benefits are the specific items and services included in the Medicare benefit package. Coverage defines the amount, duration and scope of the benefits for which the Medicare program will pay. The Medicare statute specifies the benefits to which beneficiaries are entitled in very general terms. Part A covers hospital care and related home health and skilled nursing home care. Part B covers physician and other outpatient services, including durable medical equipment. The Medicare statute lists excluded services, although now Medicare+Choice plans can provide some of these services from savings.

The Medicare statute contains a general coverage prescription that "items or services [which] are not reasonable and necessary for the diagnosis and treatment of an illness or injury, or to improve the function of a malformed body member" are not covered.[1] Decisions on whether Medicare covers an item or service are made by Medicare contractors that administer the Medicare program on behalf of the Health Care Financing Administration (HCFA) and initially adjudicate all claims for Medicare coverage and payment for beneficiaries enrolled in the fee-for-service program.[2]

Coverage policies and decisions fall into three categories depending on the type of item or service involved.

1. First is coverage policy pertaining to the amount and duration of a fairly conventional service, such as inpatient hospital care or home health services. This type of coverage policy is often implemented at the contractor level. The contractor may rely on the use of computerized screens to identify situations in which services exceed expected norms regarding amount and duration. Coverage policy for these services are contained in the applicable HCFA manual for the Medicare contractors or providers.

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[1] 42 U.S.C. § 1395y(a)(1) (1999).

[2] The Medicare contractors for Part A are insurance companies called fiscal intermediaries (FIs). For hospitals, Professional Review Organizations (PROs) conduct utilization and quality review of hospital inpatient services. The Medicare contractors for Part B are health insurance companies called carriers. In the Medicare+Choice program, the prepaid health plans contract directly with HCFA and implement coverage policy.

2. Second is coverage policy pertaining to items, namely medical devices used in the care of chronic illness or long term care. These items or devices are often sold as durable medical equipment and managed on the Part B side of the program. HCFA publishes coverage policy on these items chiefly in the list of durable medical equipment in the its *Coverage Issues Manual.*

3. Third are new medical technologies and procedures that are often experimental and come before the HCFA national office for a national coverage determination. HCFA publishes national coverage determinations in the *Medicare Coverage Issues Manual.* There is some overlap between the second and third categories of coverage policy.

In the early years of the Medicare program, coverage policy had been made chiefly by Medicare contractors at the local level. However, with the advances in expensive new medical technology, the Medicare program was faced with more issues on whether to cover new technologies which called for attention from the national office. In the early 1980s, HCFA began publishing national coverage determinations as coverage rulings in the *Federal Register* and contractor manuals.

In part, this pressure and concern came from medical device manufacturers that, as of 1976, had to get approval from the Food and Drug Administration (FDA) before marketing new medical devices to assure "the reasonable safety and effectiveness of medical devices intended for human use."[3] Medical device manufacturers were confounded when FDA approval did not necessarily result in Medicare coverage and that further review for Medicare coverage purposes was required. Beneficiaries and their physicians were concerned that their access to new technologies were limited by Medicare coverage determinations. Also many were concerned about the inconsistency of Medicare coverage policy nationwide as carriers had the authority to make coverage policy on a local basis. For example, in the early 1980s, heart transplants were covered in California but not in other parts of the country.

In 1987, as part of the settlement in *Jameson v. Bowen,*[4] which contested the application of a national coverage policy, HCFA promulgated a notice explaining its procedures for making coverage decisions.[5] In this notice, HCFA stated its intention to promulgate a rule for making national coverage determinations. In January 1989, HCFA promulgated a proposed rule establishing procedures and criteria but never published a complete final rule.[6] The rule was to establish criteria and procedures for HCFA decisions as to whether and under what circumstances specific health care technologies could be considered "reasonable" and "necessary" in more open and streamlined procedures with increased public participation and expedited procedures for "new breakthrough" technologies. In 1995, HCFA did publish a final rule with a comment period to specify conditions when Medicare would cover certain devices with an investigational device exemption through the FDA and certain services related to those devices.[7]

Previously, when making national coverage policy, HCFA conducted an internal review or consulted with its Technical Advisory Committee (TAC).[8] This committee was comprised of ten carrier medical directors, a managed care medical director, and representatives of other federal health agencies. The TAC could recommend that HCFA issue a national coverage policy, refer the issue for assessment by the Agency for Health Care Policy and Research or other qualified public or private assessment organization, postpone the decision pending more information, or make no decision. HCFA could accept or reject the TAC's recommendation. TAC proceedings were closed to the public and outside parties with an interest in the item or service under review had no opportunity to participate formally.

Many stakeholders, particularly the medical device industry, have been critical of the closed character of HCFA's coverage decision making process. In the 1980s, the Administrative Conference of the United States recommended that HCFA establish

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[3] 42 U.S.C. § 360c (1999).

[4] [1987–1 Transfer Binder] Medicare & Medicaid Guide ¶36,033 (E.D. Cal. Feb. 20, 1987) (Settlement Agreement and Release of Claims).

[5] Health Care Financing Administration, Medicare Program, Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. 15,560 (Apr. 29, 1987).

[6] Health Care Financing Administration, Medicare Program; Criteria and Procedures for Making Medical Service Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302 (Jan. 30, 1989).

[7] Health Care Financing Administration, Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 Fed. Reg. 48,417 (Sept. 19, 1995).

[8] Issues Relating to Medicare's Coverage Policy, Hearing before Subcommittee on Health, 105th Cong., 1st Sess. (1997) (Testimony Bruce C. Vladeck, Administrator, Health Care Financing Administration).

greater regularity and openness in its coverage decision making processes.[9] The American Bar Association also recommended similar reforms in Medicare coverage policy making.[10] Concerns about regularity and openness continue as troublesome issues today. GAO has been a persistent critic of HCFA's coverage decision making processes at both the national and local level.[11]

HCFA is currently redesigning its coverage decision making process. In September 1998, HCFA conducted a "town hall" on Medicare Coverage decision making and published a white paper.[12] HCFA has appointed a Medicare Coverage Advisory Committee comprised of outside experts that conducts meetings which are open to the public and at which requesters of coverage for a device or service can present their case.[13] HCFA plans to publish a notice shortly outlining the administrative process for making national coverage policy. HCFA also plans to develop general criteria that will guide in developing criteria for specific sectors of the health care industry.

BENEFICIARY APPEALS SYSTEMS UNDER THE MEDICARE PROGRAM

There are a multitude of appeals systems under the Medicare program depending on the type and status of the appellant and the subject matter of the dispute. In general, the two main types of appellants are Medicare those and Medicare providers. For Medicare beneficiaries, appeals procedures are different for beneficiaries who have enrolled in a Medicare+Choice plan under Part C and for those who have opted to remain in traditional fee-for-service Medicare under Parts A and B. For Medicare+Choice enrollees, there are grievance and appeal procedures within the managed care plan and then administrative and judicial review.[14]

Initially, the Medicare statute only permitted appeals on the part of beneficiaries with disputes over Part A services in the conventional administrative review structure of the Social Security Administration (SSA) of which the Medicare program was a part. Beneficiaries with concerns had a right to a fair hearing before the carrier. In 1972, responding to increased hospital and nursing home disputes over Medicare reimbursement, Congress established the Provider Reimbursement Review Board to adjudicate payment disputes of institutional providers.[15]

During the late 1970s and 1980s, there was increased pressure from beneficiaries and particularly providers for administrative and judicial review of Part B claims. In 1984, in *Heckler v. Ringer,*[16] the Supreme Court ruled that a beneficiary could not challenge a national coverage determination prohibiting coverage for bilateral carotid artery resections to relieve respiratory distress without exhausting administrative remedies and proceeding through the Social Security Act's appeals process. In part, beneficiaries, providers and particularly suppliers and manufacturers on their behalf wanted to challenge national coverage decisions and other Medicare coverage policy upon which claim denials were based.

Much concern was expressed about the fact that beneficiaries with Part B appeals did not have statutory administrative and judicial review but only fair hearings before carrier officials. The Supreme Court, in *Schweiker v. McClure,*[17] concluded that carrier Part B hearing procedures were sufficient and administrative review before an Administrative Law Judge (ALJ) and judicial review were not required under the procedural due process clause of the federal constitution. In 1985, the Subcommittee on Health of the Senate Finance Committee held hearings on Medicare appeals at which beneficiaries' complaints about the Part B appeals process was the central

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[9] See ACUS Recommendation 87–8, National Coverage Determinations under the Medicare Program, 1 C.F.R. §305.87–8; ACUS Recommendation 86–5, Medicare Appeals, 1 C.F.R. §305.86–5. See also Eleanor D. Kinney, National Coverage Policy Under the Medicare Program: Problems and Proposals for Change, 32 St. Louis U.L.J. 869 (1988); Eleanor D. Kinney, The Medicare Appeals System for Coverage and Payment Disputes: Achieving Fairness in a Time of Constraint, 1 Admin. L. J. (Am. U.) 1 (1987).

[10] American Bar Association, Recommendations on Medicare Procedures by the ABA House of Delegates (August 1988).

[11] See, e.g., U.S. Gen. Accounting Off., Medicare Part B: Regional Variation in Denial Rates for Medical Necessity (1994); U.S. Gen. Accounting Off., Medicare-Technology Assessment and Medical Coverage Decisions (1994).

[12] Health Care Financing Administration, How Coverage Review is Conducted: White Paper for Town Hall Meeting Held on September 25, 1998 (1999).

[13] Health Care Financing Administration, Medicare Program; Establishment of the Medicare Coverage Advisory Committee and Request for Nominations for Members, 63 Fed. Reg. 68,780 (Dec. 14, 1998).

[14] 42 U.S.C. §1395w–21 (1999).

[15] 42 U.S.C. §1395oo (1999).

[16] 466 U.S. 602 (1984).

[17] 456 U.S. 188 (1982).

theme.[18] Nevertheless, in the Omnibus Budget Reconciliation Act of 1986, Congress established administrative review for part B claims, but also imposed significant limitations on administrative and judicial review of national coverage determinations.[19]

The Part B appeals process has been problematic since its inception. HCFA stirred up controversy in the late 1980s when it determined that it would retain carrier hearings for Part B claims.[20] This proposal was unsuccessfully challenged in *Isaacs v. Bowen*[21] which upheld HCFA's authority to retain this step. Then HCFA sought to create an administrative law judge corps within HCFA to adjudicate Part B disputes but backed away from the concept in the face of vigorous opposition on many fronts.[22] HCFA never implemented these plans. A GAO report found that the Part B administrative appeals process during these early years was quite lengthy.[23] Many are concerned about the Part B appeals process,[24] including the American Bar Association.[25] Problems have continued to surface in judicial decisions as well.[26] HCFA has acknowledged the need for reform.[27]

Medicare Fee-For-Service Appeal Procedures

Below are described the current appeal procedures for beneficiaries dissatisfied with determinations under Parts A and B of the Medicare program and who have elected the fee-for-service Medicare option.

Part A. Under Medicare Part A, which funds inpatient hospital and related post hospital services, beneficiaries may obtain administrative and judicial review of denied claims. For claims involving hospital services and utilization review determinations, beneficiaries must seek reconsideration before the Peer Review Organization (PRO). For claims over $200, beneficiaries may appeal adverse PRO determinations to an SSA ALJ and seek judicial review of adverse administrative decisions for claims of $2,000 or more.[28]

For all other beneficiary appeals under Part A, the beneficiary seeks reconsideration of the FI's determination. For claims involving $100 or above, they may appeal to an SSA ALJ with judicial review for claims of $1,000 or above.[29]

Part B. It should be emphasized that the right to appeal is for beneficiaries only and providers have rights to appeal only if they have accepted assignment of the beneficiaries claim and stand in the shoes of the beneficiary. The Part B appeals process retains the fair hearing proceeding before the carrier.[30] After the carrier's final disposition, a beneficiary may appeal an adverse determination if the amount in controversy is $500 or more to an SSA ALJ.[31] Judicial review is available for disputes of $1,000 or more.

Review of National Coverage Determinations. The Omnibus Budget Reconciliation Act of 1986 imposed significant limitations on the review of national coverage deter-

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[18] Medicare Appeals Provisions: Hearings Before the Subcomm. On Health of the Senate Comm. On Finance, 99th Cong., 1st Sess. (1985).

[19] 42 U.S.C. § 1395ff (1999).

[20] Health Care Financing Administration, Medicare Carriers Manual § 12195B (1986).

[21] 865 F.2d 468 (2d Cir. 1989).

[22] See Oversight Hearing on Adjudicatory Procedures of the Dep't of Health & Human Services Before the Subcomm. on Administrative Law and Government Relations of the House Judiciary Comm., 101st Cong., 1st Sess (1989).

[23] U.S. General Accounting Office, Statistics on the Part B Administrative Law Judge Hearings Process (1989).

[24] See, e.g., Judith G. Waxman & Alfred J. Chiplin, Jr., Medicare Part B Appeals—and You Thought the System was Fixed, Clearinghouse Rev. 384 (Special Issue, Summer 1989); Bess M. Brewer, Risky Business: Five Years of Navigating the Medicare Part B Appeals Process, Clearinghouse Rev. 537 (Sept. 1992) (raising beneficiary concerns); Timothy P. Blanchard, Medical Necessity Denials as a Medicare Part B Cost-Containment Strategy: Two Wrongs Don't Make it Right or Rational, 34 St. Louis. U.L.J. 939 (1990) (raising provider concerns).

[25] American Bar Association, Recommendations on Medicare Procedures by the ABA House of Delegates (August 1988).

[26] See, e.g, Warder v. Shalala, 149 F.3d 73 (5th Cir. 1998); Friedrich v. Secretary of Health and Human Services, 894 F.2d 829 (6th Cir. 1989); Mathews v. Shalala, 1997 WL 124106 (S.D.N.Y., Mar. 18, 1997); Cedars-Sinai Medical Center v. Shalala, 939 F.Supp. 1459 (C.D. Cal. 1996); Bosko v. Shalala, [Transfer Binder 1997–1] Medicare & Medicaid Guide ¶45, 139 (W.D. Pa. Aug. 28, 1996).

[27] Medicare Appeals Process: Hearings before the Subcomm. On Health of the House Comm. On Ways and Means, 105th Cong., 2d Sess. (Apr. 23, 1998) (Testimony of Michael M. Hash, Deputy Director, Health Care Financing Administration).

[28] 42 U.S.C. § 1320c–4 (1999).

[29] 42 U.S.C. § 1395ff (1999).

[30] 42 U.S.C. § 1395u (1999).

[31] 42 U.S.C. § 1395ff(b)(2) (1999).

minations.[32] Specifically, review of the coverage of any particular type or class of items or services is subject to the following limitations. Specifically, an ALJ may not review a national coverage determination. A court shall not set aside or invalidate a national coverage determination on grounds that requirements in the Administrative Procedure Act[33] relating to publication in the Federal Register or opportunity for public comment were not satisfied or that Medicare's rulemaking requirements[34] were not followed. Further, in any case in which a court determines that the record is incomplete or otherwise lacks adequate information to support the validity of a national coverage determination, it shall remand the matter to the Secretary for additional proceedings to supplement the record and the court may not determine that an item or service is covered except upon review of the supplemented record.

Medicare+Choice Appeal Procedures for Beneficiaries

Medicare+Choice plans must have "meaningful grievance procedures" with organizational determinations made by health plans and external review for reconsiderations.[35] The Secretary shall contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage. Following external review, there is administrative review before an SSA ALJ with subsequent judicial review.

THE CURRENT CONTROVERSY

The process for making Medicare coverage policy as well as adjudicating coverage in the cases of individual Medicare beneficiaries has been controversial. The historical development of the procedures for making Medicare policy and adjudicating appeals over its applications reflects this controversy. The reason for the controversy in the past and, especially for the future, is the collision of four forces:

- The increased provision of expensive care in outpatient settings and thus coming under the Part B side for claims administration and adjudication.
- The incredible advances in medical technology for the diagnosis and treatment of disease since the 1960s. However, this advance pales in terms of anticipated advances in medical technology in the future.
- The continuing inflation in Medicare program expenditures that threatens the solvency of the Medicare trust funds and puts great pressure on the federal budget of which Medicare constitutes a significant component.
- The increasing numbers of Medicare beneficiaries due to demographic changes in the elderly population as potential consumers of newly approved technologies.

It is worth looking at the interaction of these forces in some detail. The issue of technology is especially problematic for the Medicare program because it potentially translates into increased program expenditures with resulting pressures on Medicare trust funds and other sources of financing. The stewards of the Medicare program must be cognizant of these developments in formulating coverage policy for the Medicare program as expanded coverage for any item or service potentially contributes to increased program expenditures particularly if used in the care of many beneficiaries.

The battle over Medicare coverage policy is currently being fought out in the Part B appeals process. Beneficiary or, more likely, providers and suppliers who have accepted assignment from beneficiaries and are appealing on their behalf, are challenging the denial of Part B claims. There are two major types of issues in Part B appeals which need attention:

- Special situations in which the beneficiary could really benefit from a non-covered item or service in a cost effective treatment.
- Coverage policy applied to new technologies that inappropriately stifles development of medical innovation and hurts the legitimate business interests of device manufacturers.

The current Part B Appeals Process is not capable of adjudicating either type of issue. In neither case is the beneficiary or the manufacturer able to obtain the relief they desire. Regarding the application of coverage policy to beneficiaries in the first situation, at no point in the appeals process does a decision maker have any flexibility whatsoever to allow a prescribed item or service that might be of great benefit to a beneficiary and even save Medicare expenditures in the care of that beneficiary.

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[32] 42 U.S.C. § 139ff(c) (1999).
[33] 5 U.S.C. §§ 551–559 (1999).
[34] 42 U.S.C. § 1395hh(b) (1999).
[35] 42 U.S.C. § 1395w–21 (1999). See Jennifer E. Gladieux, Medicare+Choice Appeal Procedures: Reconciling Due Process Rights and Cost Containment, 25 Am. J. L. & Med. 61 (1999).

Regarding the impact on the manufacturers of new technologies, the appeal procedures do not provide a decision-maker at any level with authority to overturn a national coverage determination. Even if an appeal comes before a federal court, the court must remand the policy back to HCFA for amplification and further development of the record.

Finally, for all Part B appeals, the appeals process is quite long with an internal appeal before the Medicare contractor and then administrative review and judicial review. It often takes many months—well over a year—to get through these layers of review.[36] A cumbersome process with no possibility of relief is frustrating and counter productive to all parties concerned.

IDEAS FOR REFORMS

In contemplating reforms, it is useful to identify the affected stakeholders and their legitimate interests in the Medicare coverage decision making process. The most important stakeholder is the Medicare beneficiary who has a legitimate interest in getting the best available treatment when in need.

The second stakeholder is HCFA, which stands in the shoes of Medicare beneficiaries who finance the Part B program with Part B premiums as well as current workers who finance Part B with their taxes. HCFA's interest is ensuring that it purchases health care services for beneficiaries in a cost effective manner. Such stewardship includes paying only for items or services that are proven to be effective in the treatment of illness and injury and not for items or services that are experimental or ineffective. HCFA has argued historically that the Medicare program should not finance the research and development of medical devices or procedures—hence its strict adherence to the coverage exclusion of experimental items or services.

The third stakeholder is the provider community which has an interest in having the ability to use and prescribe the best treatment available for Medicare patients without the specter of administrative hassles in getting paid from the Medicare program. Institutional providers want to be able to purchase medical devices and other supplies without being tied up in subsequent coverage disputes and payment denials.

The fourth stakeholder is the medical device manufacturing industry which has an interest in bringing new products to market in an efficient and profitable manner. The device industry faces two regulatory barriers before getting a product to market: the device review process in the FDA[37] and the Medicare coverage decision making process. This latter process has a great impact on their ability to make a profit on their product and recoup their development costs. Understandably, device manufacturers want predictable, non-duplicative and efficient regulatory approval procedures to conserve expenses and get to market quickly.

Reform should proceed along the two major strategies: (1) reform of the Medicare coverage policy making process to make coverage policy in an open, accessible, expeditious and accurate manner, and (2) reform the appeals process to adjudicate cases in an expeditious manner. In my judgment, the two processes are joined at the hip. A well designed, open policy making process in which all interested parties can participate effectively and present their positions before responsible parties is the appropriate way to make coverage policy. Such a reformed process will alleviate the need for many to bring appeals. If the policy making process has sufficient credibility, disappointed requesters many not pursue some negative coverage decisions in the appeals process.

Reforms for the HCFA Coverage Decision Making Process

The HCFA coverage policy making process is the forum in which to determine whether a new medical procedure or device should be a covered Medicare benefit. The determination of this issue always involves the consideration of difficult "legislative" facts such as the cost implications of coverage and the medical benefit of new technology for beneficiaries. The HCFA coverage making process should be designed to marshal the best medical and scientific evidence available in the scientific literature and the results of relevant clinical trials. The process should obtain the scientific advice available both inside and outside of government. HCFA's establishment of the Medicare Coverage Advisory Committee is an excellent step in moving toward a sound policy making process.

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[36] Medicare Appeals Processes: Hearings Before the Subcommittee on Health House Committee on Ways and Means, 105th Cong., 2d Sess. (Apr. 23, 1998) (Testimony of Michael M. Hash, Deputy Director, Health Care Financing Administration).

[37] 42 U.S.C. §360c (1999).

Further, the HCFA coverage decision making process must allow for input from the individual or company promoting coverage of a medical device or procedure as well as other individuals or organization, such as medical specialty societies, other provider organizations and patient advocacy groups, with an interest in the coverage issue. These parties should have an opportunity to provide adequate written and possibly oral input in the coverage decision making process. This openness is critical to give the process credibility among affected parties, including the medical device industry, the provider community and beneficiaries.

HCFA might also consider making "probationary" coverage determinations that allow for a device or procedure to be tested and evaluated on a demonstration basis before a final coverage determination is made. Such a probationary procedure would have to be carefully designed to control Medicare expenditures for unproven medical technologies and would probably be used in only a few instances.

The following principles should guide the design of the coverage decision-making process from a procedural perspective:

- HCFA should provide adequate notice that its coverage decision making process is going to consider a national coverage determination or other coverage policy regarding a particular device or procedure. The notice should be provided in a manner likely to reach beneficiaries, providers, suppliers and device manufacturers.
- Requestors of Medicare coverage for a medical device or procedure, namely a medical device manufacturer, should have an adequate opportunity to present their case in oral and written form to the Medicare Coverage Advisory Committee and also to the officials in HCFA that will actually decide on the coverage policy.
- All other individuals or organizations, such as medical specialty societies, other provider organizations and patient advocacy groups, with an interest in the coverage issue should have an opportunity to provide adequate written and possibly oral input in the proceeding for making coverage policy.
- To the extent possible, the coverage decision making process should not impose requirements or otherwise duplicate the FDA device approval process.

Reforms of the Medicare Part B Appeals Process

Again, the current Part B appeals process is the battle ground on which the current disputes over the appropriateness of Medicare coverage policy regarding medical devices and procedures is being waged. The appeals process is not the proper forum for resolving issues of the validity or appropriateness of any given policy and, in particular, Medicare coverage policy. Neither ALJs nor federal judges have the technical expertise nor the broader perspective in the context of a single case to make decisions involving the correctness of a Medicare coverage policy.

Nor are current appeals systems adequate to address the claims of beneficiaries that have unique circumstances and could benefit from a particular non-covered item or service. For example, HCFA might specify that carriers could provide coverage for a specified non-covered item for beneficiaries with particular needs and where other covered treatments have failed. Many insurance companies and managed care organizations provide non-covered services on this basis. Ideally, the carrier could be accorded the discretion to decide such cases and also to establish the requisite case management oversight to ensure the safety of the beneficiary and conserve Medicare dollars. The carrier fair hearings might appropriately be used to appeal such special situations when the carrier has already denied coverage.

The following principles should guide reform of the Part B appeals process:

- The interests of beneficiaries should be paramount and appeals procedures should be designed to adjudicate their concerns effectively.
- Appeal procedures should be as streamlined as possible and extra layers of review should be implemented only if they serve a particular purpose required to facilitate the expeditious and fair resolution of the disputes.
- ALJs and other adjudicators should not have authority to consider the validity of Medicare coverage policy and, in particular, national coverage determinations.

In sum, the Part B appeals process is not the forum to adjudicate the validity or appropriateness of HCFA coverage policy. It has been called to do so because the national coverage policy process to date has been inadequate to provide a forum for interested parties, including beneficiaries, providers and device manufacturers to raise their concerns and arguments regarding the coverage of a new medical device or procedure in the first instance.

However, the question remains as to what appeal procedures and forums should be available to enable providers, device manufacturers and other interested parties to challenge HCFA's decision on the coverage of a particular medical device or pro-

cedure. In *Chevron, U.S.A., Inc. v. National Resources Defense Council,*[38] the Supreme Court established the principle that reviewing federal courts have limited authority to overturn agency policies and interpretations of their enabling legislation. The Court's rationale for its clear preference for limited judicial review of agency policy is that the agency has ultimate responsibility to manage the statutorily mandated program and needs to have the authority to make the requisite policies and decisions to carry out their statutory assignments.

In sum, Congress should think carefully about the implications of giving final authority over Medicare coverage policy to a court or other decision maker that is not accountable for the fiscal performance of the Medicare program or the safety and welfare of its beneficiaries. The better approach, in my judgment, is to focus on improving HCFA's Medicare coverage decision making process in the first instance to make it truly open to beneficiaries and their providers and the developer of new medical technologies that are so important in the advance of medical care.

CHRONOLOGY

Key Legislative Developments

Social Security Amendments of 1965, Pub. L. No. 89–97 (1965).
- Establishing the Medicare program is established with appeal rights only for beneficiary concerns over hospital services.

Social Security Amendments of 1972, Pub. L. No. 93–603 (1972).
- Expanding Medicare eligibility to include the disabled on the Social Security Disability Insurance Program.

Medical Device Amendments of 1976, Pub. L. No. 94–295 (1976).
- Establishing FDA approval of medical devices.

Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97–248 (1982).
- Establishing the Peer Review Organization Program with Peer Review Organizations to review hospital expenditures.

Social Security Amendments of 1983, Pub. L. No. 98–21 (1983).
- Establishing the DRG Prospective Payment System for Hospitals.

Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99–509 (1986).
- Authorizing Administrative and Judicial Review for Part B Claims.
- Establishing Special Rules for Appeals of National Coverage Determinations.

Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101–239 (1989).
- Establishing Resource-Based, Relative Value Scale for determining Medicare payment to Physicians.
- Establishing the Agency for Health Care Policy and Research with the authority to conduct technology assessments.

Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103–66 (1993)
- Reforming Payment Methods for Durable Medical Equipment.

Budget Balanced Budget Act of 1997, Pub. L. No. 105–33, 111 Stat. 251 (1997).
- Establishing the Medicare+Choice Program (Part C) to replace the Medicare HMO program.

Key Rules and Notices on Medicare Coverage Policy Making Procedures

Health Care Financing Administration, Medicare Program, Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. 15,560 (Apr. 29, 1987).

Health Care Financing Administration, Medicare Program; Criteria and Procedures for Making Medical Service Coverage Decisions That Relate to Health Care Technology, 54 Fed. Reg. 4302 (Jan. 30, 1989).

Health Care Financing Administration, Medicare Program; Criteria and Procedures for Extending Coverage to Certain Devices and Related Services, 60 Fed. Reg. 48,417 (Sept. 19, 1995).

[38] 467 U.S. 837 (1984).

Health Care Financing Administration, Medicare Program; Establishment of the Medicare Coverage Advisory Committee and Request for Nominations for Members, 63 Fed. Reg. 68,780 (Dec. 14, 1998).

MAJOR CONGRESSIONAL HEARINGS ON APPEALS

Medicare Appeals Provisions: Hearings Before the Subcomm. On Health of the Senate Comm. On Finance, 99th Cong., 1st Sess. (1985).

Oversight Hearing on Adjudicatory Procedures of the Dep't of Health & Human Services Before the Subcomm. on Administrative Law and Government Relations of the House Judiciary Comm., 101st Cong., 1st Sess (1989).

Issues Relating to Medicare's Coverage Policy, Hearing before Subcommittee on Health of the House Comm. On Ways and Means, 105th Cong., 1st Sess. (April 17, 1997).

Medicare Appeals Processes: Hearings Before the Subcommittee on Health House Committee on Ways and Means, 105th Cong., 2nd Sess. (Apr. 23, 1998).

The Medicare Coverage Process and Beneficiary Processes: Hearings Before the Subcommittee on Health House Committee on Ways and Means, 106th Cong., 1st Sess. (Apr. 22, 1999).

Chairman THOMAS. Thank you very much, Professor Kinney. Mr. Coleman.

STATEMENT OF TERRY COLEMAN, J.D., PARTNER, FOX, BENNETT & TURNER

Mr. COLEMAN. Thank you, Mr. Chairman. Since I have worked as a lawyer both at HCFA and in the private sector, I hope that I can provide some useful information to the Subcommittee from those two perspectives, and I will summarize a few issues.

The first issue is who should make Medicare coverage policy? The unusual aspect of Medicare's current process for making coverage decisions, as we have heard, is its decentralized nature. The Medicare contractors independently interpret and apply Medicare's requirements and make most of the coverage decisions. I believe this deference to the contractors is historically based, in part, on HCFA's view that Congress wanted the contractors to be relatively independent and to make decisions based on local medical practice, and we heard about that earlier. The result of this decentralized process is that Medicare coverage varies depending on location. The degree of variation is not necessarily extreme, but conditions for coverage clearly vary from State to State, and items and services covered in one State will not necessarily be covered in other States.

In recent years, HCFA has recognized that this is not entirely a desirable practice and has attempted to increase uniformity. But much of this effort has not taken the form of additional national coverage decisions but instead greater coordination of actions by the carriers, such as in developing model policies. Increasing uniformity through joint carrier actions rather than decisions by HCFA has serious procedural disadvantages, in my view. First, the carriers use a relatively nonpublic process in which the opportunity for input is limited, and, perhaps, most troubling is that coordinated action by the contractors amounts to the making of national Medicare policy by nongovernment employees who are not accountable through the normal process of administrative and congressional oversight.

Second issue, the opportunity for public input in coverage policy decisions. The process for making coverage decisions is informal. Under the Medicare statute, national coverage decisions are exempt from the notice and comment rulemaking requirements that ordinarily apply to substantive agency policies. When I was at HCFA, I was involved in the 1986 legislation that enacted this exemption. Its primary purpose was to permit national coverage decisions to be made more quickly than the 2 years or so it takes to put out a regulation, and if the national coverage decision process is to remain viable for more than occasional use, there has to be a process other than full rulemaking. But even though it shouldn't involve full rulemaking, HCFA's announcement today to allow for greater public input is a major improvement over the current relatively closed process. The objective should be to develop a procedure that allows the public an opportunity to know what HCFA is considering; to place items on HCFA's agenda; to submit information; to respond to any concerns that HCFA may have, and to receive a timely decision. To the extent that the contractors remain involved in coverage decisions, they, too, should be subject to a more open process that allows for broader public participation.

The third issue is a need for a comprehensive statement in the regulations of the criteria that HCFA and the contractors are to use in making coverage decisions. At present, there is no clear statement of the policy on many fundamental issues, such as what is considered an experimental procedure? What are the criteria used to determine whether a particular service is considered medically necessary? What discretion, if any, do the carriers have to deny coverage of a drug for conditions approved by the FDA? And numerous other issues. The lack of clearly defined criteria creates a great deal of confusion, especially under the decentralized process in which the carriers, operating on their own, continue to play a major role in making Medicare policy.

Finally, the issue of judicial appeals. Initially, the only appeals mechanism in the statute for part B coverage denials was a hearing before the Medicare carrier; no judicial review was allowed. In 1986, though, the Supreme Court unanimously held in the *Michigan Academy* case that judicial review of Medicare part B policies was available. The Court ruled that Congress intended to bar judicial review only when the issue was a specific dollar amount and that beneficiaries could challenge Medicare regulations and policies directly in court. At about the same time the Supreme Court greatly expanded Medicare part B judicial appeal rights in this way, however, Congress amended the Medicare statute to create an appeals system for part B that is parallel to the system for part A. Under this process, beneficiaries and others who want to appeal coverage policies must go through a series of administrative hearings that we have heard about on specific denied claims, and that process can take 2 years or more. So, ironically, the 1986 amendment, which was seen as expanding appeal rights, had the effect of diminishing judicial appeal rights by forcing all appeals into the very lengthy ALJ process. As a practical matter, the Supreme Court's holding was overruled by Congress, perhaps unintentionally, and there is no longer an effective means to challenge HCFA's coverage policies. In my view, Congress should consider restoring

the rights of beneficiaries and other interested parties to obtain direct judicial review of national coverage decisions as the Supreme Court at one time said existed.

Thank you, Mr. Chairman.

[The prepared statement follows:]

Statement of Terry Coleman, J.D., Partner, Fox, Bennett & Turner

MEDICARE PROCESS FOR COVERAGE DECISIONS AND BENEFICIARY APPEALS

Thank you for the opportunity to testify regarding the Medicare process for coverage decisions and appeals. Since I have worked as a lawyer for the Health Care Financing Administration (HCFA) and its parent Department of Health and Human Services, and subsequently have practiced in the private sector, I hope I can provide some useful information for the Committee based on that combined perspective. This statement represents my personal views and not necessarily those of my current or past clients.[1]

DECENTRALIZED PROCESS FOR MAKING COVERAGE DECISIONS

A threshold question in considering the Medicare coverage process is who should make the policies. The unusual aspect of Medicare's current process for making coverage decisions is its decentralized nature. The Medicare claims processing contractors—the carriers and fiscal intermediaries—independently interpret and apply Medicare's requirements. In addition, in a relatively small number of cases, HCFA's Central Office issues national coverage decisions that apply everywhere. The result of this largely decentralized process is that Medicare coverage varies depending on location. The degree of variation is not necessarily extreme, but conditions for coverage of certain items and services clearly vary from state to state, and items and services covered by Medicare in some states may be denied coverage in other states.

The Medicare contractors not only interpret how Medicare policy applies to particular claims—which they must inevitably do—but they also issue broad policies. HCFA expressly authorizes the contractors to develop "local medical review policies" that define what each carrier considers to be a medically necessary use of an item or service. The contractors also interpret other provisions of Medicare law when there is no national interpretation.

The policy of decentralization stems, I believe, from two factors—a long-standing interpretation about the respective roles of the contractors and HCFA intended by Congress, and the inability of the HCFA Central Office to take on a larger workload. The first factor derives from the fact that the Medicare statute, from its enactment in 1965, has required the program to use insurance companies to process claims and administer the program. This provision led to the view within HCFA and its predecessor agency that Congress wanted the contractors, rather than the federal government, to make many of the detailed decisions about administration of the program. This view was fortified by the way in which the statute was drafted. In particular, section 1842 of the Act, which describes how the carriers are to administer the Part B program, imposes certain responsibilities directly on the carriers, rather on the Secretary as statutes are ordinarily worded. This language led some in HCFA to believe that the agency was limited in the extent to which it had authority to control decisionmaking by the carriers. While this view has undoubtedly diminished in recent years, I believe the historical notion that HCFA should refrain from too much control over the contractors' policies explains much of the current arrangement. Also influencing deference to the contractors was the belief that medical practice varies regionally and that local carriers are in the best position to adjust coverage policy to reflect those regional variations.

The other factor leading to decentralization was the relatively small staff at the HCFA Central Office. Since the staff is able to make comparatively few national coverage decisions, and the carrier medical directors have been available to fill any decisionmaking void, it has been easy to defer to the contractors' decisions.

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[1] In accordance with the Committee's rules, I state that I have not received any Federal government grants or contracts during the current or past two fiscal years, and that I am not representing any entities in my appearance before the Committee. I am currently a partner in the Washington, D.C. law firm Fox, Bennett & Turner, where I have practiced since 1989. Prior to that, I held various positions in the Department of Health and Human Services, including Deputy General Counsel (1981–86), Acting General Counsel (1984–85), Chief Counsel of HCFA (1986–88), and Deputy Administrator of HCFA (1988–89).

The decentralized decisionmaking process results in a lack of uniformity in coverage policy that is difficult to defend. It would seem desirable for Medicare beneficiaries to have the same benefits regardless of where they live. Although medical practice clearly varies regionally, this variation is usually seen as an undesirable result of differences in practice style rather than being scientifically based. In addition, the decentralized process makes it difficult for persons interested in Medicare coverage of a new technology to present information to the program. If HCFA does not issue a national coverage decision, individual medical directors all over the country separately consider the data, consult with their own experts, and arrive at independent conclusions.

In recent years, HCFA has recognized the undesirable aspects of nonuniform coverage policies and has attempted to increase the degree of uniformity. Much of this effort has not taken the form of additional national coverage decisions, however, but instead greater coordination of actions by the carriers. For example, the four durable medical equipment regional carriers jointly developed their extensive coverage manual. Carrier medical directors often hold meetings under the auspices of HCFA at which they exchange views on coverage policy with an eye toward increasing uniformity. The carriers have formed workgroups which have issued "model" coverage policies intended for adoption by all carriers.

Increasing uniformity through joint carrier action rather than national coverage decisions by HCFA has serious procedural disadvantages. The carriers use a relatively non-public process in which the opportunity for input is limited. In addition, if a national organization seeks to influence coverage policy, it is difficult to learn what individual carriers are doing and to deal with the many carriers involved. Perhaps most troubling is that coordinated action by the contractors amounts to the making of national Medicare policy by non-government employees who are not accountable through the normal process of administrative and congressional oversight.

There is some debate in the provider community as to whether increased issuance of national coverage decisions by HCFA is desirable. Those who are reluctant to see greater involvement by the HCFA Central Office fear that HCFA may act unreasonably, and that the decentralized process, offering the possibility that at least some carriers will act reasonably, is better. My personal view is that HCFA should issue more national coverage decisions, provided that, as I will discuss later, it does so with an open process and there is a practical opportunity for judicial review of the decisions.

It would be useful if Congress clarified the respective roles of the contractors and HCFA in establishing coverage policy. It is one thing for HCFA to rely on the contractors because its staff size is inadequate to handle all the questions. It is another thing altogether for HCFA to defer to the independent decisions of the contractors because HCFA may believe that Congress wants coverage decisions to reflect supposed regional differences in medical practice or that Congress prefers coverage decisions to be made by the contractors rather than by HCFA. If Congress believes in the desirability of uniform Medicare coverage policy throughout the country to the extent possible, it could make that direction to HCFA clear.

Also, to the extent that the contractors retain authority to make policy, Congress may want to address whether they should, in effect, be permitted to make national policy without HCFA's involvement by developing joint policies with other contractors.

Opportunity for Public Input in Coverage Policy Decisions

The process for making decisions about coverage policy is informal both at HCFA and at the contractors. In 1986, Congress revised the Part B Medicare appeal procedures and in the process exempted national coverage decisions from the notice and comment rulemaking requirements that ordinarily apply to substantive agency policies.

I was involved in the 1986 legislation on behalf of HCFA and am familiar with the background of this exemption. Its purpose was twofold. First, since the legislation was establishing a new procedure for judicial review of Medicare Part B decisions, including coverage policies, there was a concern that the pre-existing body of coverage decisions would be found procedurally defective. HCFA and its predecessor agency had issued a large number of national coverage decisions since the beginning of the Medicare program. Those decisions were not issued after notice in the Federal Register and opportunity for public comment, and there was little or nothing otherwise in the form of an administrative record that would explain and support the decisions. Accordingly, without the exemption, there was the possibility that many completely sound decisions would be overturned because of a failure to comply with the Administrative Procedure Act.

In addition to the concern that the existing body of national coverage decisions would be placed in jeopardy by the new appeals process, there was also concern that national coverage decisions should be allowed to be made without burdening the process with the requirements that the Administrative Procedure Act imposes on new regulations. HCFA's experience, like that of many other federal agencies, is that the rulemaking process—developing and publishing a proposed regulation, reviewing and developing a written response to the comments received, and publishing the final version—typically takes two years or more and requires extensive effort. If the national coverage decision procedure were to remain viable for more than occasional use, there had to be a process other than full rulemaking.

While it remains desirable that national coverage decisions should be exempt from full rulemaking, HCFA's announcement several months ago that it will revise its procedures to allow for greater public input is a major improvement over the current relatively closed process. The objective should be to develop a procedure that allows the public an opportunity to know what HCFA is considering, to place items on HCFA's agenda, to submit information, to respond to any concerns that HCFA may have, and to receive a timely decision.

The procedures used by the contractors to develop coverage policy are also informal. In the case of local medical review policy, the contractors are required by HCFA to present proposals to a Carrier Advisory Committee that consists of physician representatives and to circulate the proposal to local medical organizations for comment. The degree to which these comments influence the outcome appears to vary from contractor to contractor, but in many cases it has proved to be a useful process. A significant deficiency, however, is that proposals are distributed only to selected local physician and provider groups and not to beneficiary or national organizations that might have an interest in the matter.

In the case of coverage decisions that are not considered local medical review policies, the contractors' decisionmaking may be an entirely closed process. Interested parties may not learn of the policy until it is announced. Some of the carriers' joint efforts I discussed earlier, such as the development of model policies, have also been conducted essentially in secret.

It would be desirable if Congress developed an administrative process for HCFA's use in making coverage decisions that struck a balance by providing an opportunity for public input without burdening the process with rulemaking-type requirements that make it useless as a practical matter. To the extent that the contractors remain involved in making coverage decisions, they too should be subject to a more open process, and a process that allows for the participation of the public, including beneficiary and national organizations.

Criteria for Coverage

There is no comprehensive statement in the Medicare regulations of the criteria that HCFA and the contractors are to use in making coverage decisions. In addition, the provisions in the Medicare manuals that discuss various aspects of coverage policy are often incomplete or ambiguous. As a result, there is no clear statement in any official Medicare publication of the policy on such fundamental issues as what is considered an experimental procedure, what are the criteria used to determine whether a particular service is considered medically necessary, the discretion if any that carriers have to deny coverage of a drug for conditions approved by the Food and Drug Administration, and many other common issues. The lack of clearly defined criteria for coverage creates much confusion, especially under the decentralized system in which carriers continue to play a major role in applying Medicare policy.

HCFA attempted to remedy this situation in the 1980s by developing a Federal Register notice to set forth the process and criteria for Medicare coverage. Although this document was published as proposed regulations in 1989, it has never been finalized, and HCFA apparently plans to begin over again.

It is essential that HCFA regulations clearly set out in detail the general rules and criteria for Medicare coverage. If the regulations were sufficiently clear and comprehensive, they would eliminate many of the disputes with the contractors, which develop their own interpretations of the Medicare statute and policy in the absence of any guidance from HCFA.

The absence of comprehensive regulations means that the Medicare carriers differ not only on how they apply Medicare policy to particular services but they even differ on the policy they purport to apply. A recent example I am aware of is the policy on what type of clinical studies reported in the medical literature should be required to support Medicare coverage of an approved drug being used in a manner not included in the Food and Drug Administration-approved labeling. Some carriers insist

on there being Phase III studies reported, while other carriers are more flexible and consider all types of studies. This does not seem to be a matter on which there should be state-by-state differences in policy. Another example is that carriers differ in whether they deny coverage of certain drugs that can be administered subcutaneously because they differ in their definition of what is excluded from coverage as a self-administered drug. Broad principles of Medicare coverage such as these should be decided at the national level by HCFA, rather than being left for independent decision by each Medicare contractor.

If the HCFA Central Office lacks the resources to deal with issues, it should consider other ways to reach nationally uniform policies rather than always delegating authority to the contractors. For example, a topic on which HCFA could ease its burden is determining which "off-label" uses of drugs should be covered. Many drugs are used by physicians for purposes not included in the labeling as approved by the Food and Drug Administration. HCFA's general policy is that each carrier can determine whether a particular off-label use is appropriate and, if so, Medicare will cover the use. Because this approach results in non-uniform and sometimes ill-considered decisions by carriers, Congress in 1993 amended the Medicare statute to establish rules for coverage of off-label uses of drugs used in cancer chemotherapy. Under the statute, Medicare must cover such drugs if the off-label use in question in listed in one of the major drug-use compendia or is otherwise supported by clinical studies published in peer-reviewed scientific literature. The compendia base their monographs on a review of the literature and are considered scientifically sound. HCFA could administratively adopt the same policy for all drugs but for some reason has chosen not to do so. This would seem to be an opportunity for HCFA to establish uniform rules for Medicare coverage based on the scientific literature with little effort.

Appeals of Coverage Decisions

The Medicare statute allows beneficiaries who have been denied coverage of an item or service to appeal that decision through a series of administrative appeals and then into federal district court if the increasing jurisdictional amount prerequisite is satisfied at each step of the appeals process. The process differs slightly between Medicare Part A and Medicare Part B, but I will focus on Part B, since disputes and appeals are relatively rare with respect to coverage of Part A services.

When the Medicare statute was first enacted, the only appeals mechanism for Part B coverage denials was a hearing before the Medicare carrier for disputes involving at least $100. No judicial review was allowed because, the legislative history indicates, Congress assumed that Part B disputes would involve small amounts of money that did not warrant burdening the federal courts with additional litigation.

Subsequently, the courts added further remedies. Although Congress had established no administrative hearing for cases worth less than $100, a court held that constitutional due process required an oral hearing, and HCFA therefore created one.[2] More important, in June 1986 the Supreme Court held in the *Michigan Academy* case that, because the availability of judicial review was to be presumed in the absence of clear congressional intent to the contrary, judicial review of Medicare Part B policies was available.[3] The Court held that Congress intended to bar judicial review only of cases in which the issue was a specific dollar amount, and that beneficiaries and others could challenge Medicare regulations and policies.

At about the same time that the Supreme Court greatly expanded Part B judicial appeal rights, Congress was considering the issue of Part B appeals. In October 1986, the Medicare statute was amended to create an appeals mechanism for Part B that is parallel to the appeals system for Part A. Under this system, the individual appealing first requests reconsideration of the denial. This "review" step is frequently the first time the carrier has actually considered the claim, since the initial denial may have been by computer. If the claim is still denied after review, the appeal goes to an informal hearing before an employee of the carrier and, if the claim is denied again, to a hearing before an administrative law judge. Many appeals are resolved favorably to the appellant at the carrier hearing or administrative law judge stages, but the appellant can proceed to federal district court if he is still dissatisfied and the amount in dispute is at least $1000.

The 1986 legislation that created the Part B appeals mechanism included some special provisions related to national coverage decisions. The law provides that national coverage decisions may not be reviewed by administrative law judges; that national coverage decisions may not be overturned because they were not issued

[2] *Gray Panthers v. Schweiker*, 652 F.2d 146 (D.C. Cir. 1980), 716 F.2d 23 (D.C. Cir. 1983).
[3] *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986).

through the Administrative Procedure Act process; and that if a court determines that the administrative record underlying a national coverage decision is inadequate, it must remand the matter to HCFA for additional proceedings to supplement the record before the court rules.

As I discussed earlier in connection with the exemption from notice and comment rulemaking requirements, these provisions were intended to address two concerns—protecting the past national coverage decisions from being overturned because of the manner in which they were issued, and maintaining some informality in the process for issuing national coverage decisions. The compromise adopted in the statute subjects national coverage decisions to judicial review, but if the administrative record is deemed inadequate to support the decision, HCFA is given an opportunity to supplement the record before the court rules on whether the record, as so supplemented, supports the decision. As a prospective matter, this process was intended to allow HCFA to avoid the burden of developing an extensive administrative record for national coverage decisions that may not be controversial. In the event that a decision thought to be simple is challenged, HCFA can attempt to defend its decision by supplementing the record. If Congress revises the process for making coverage decisions, it should consider retaining this or some similar mechanism to allow HCFA to make national coverage decisions promptly, while still allowing for appropriate judicial review.

Ironically, the 1986 amendments had the effect of diminishing appeal rights for challenges to broad Medicare policies. As I indicated earlier, just a few months prior to the enactment of the amendments, the Supreme Court had allowed direct challenges to Medicare policies as long as particular claims were not involved. Since the 1986 amendments forced appeals into the administrative law judge process, however, almost all courts have since ruled that direct challenges to agency policies are no longer available. As a result, any challenge to a Medicare Part B regulation or policy must now take the form of an appeal of particular denied claims and must be appealed through the entire administrative appeals mechanism—a process that can easily take two years or more—even though the officials involved in the administrative appeal have no authority (and should have no authority) to overturn a national coverage decision. Only after two years or more of a pointless administrative process can the policy be challenged in court. Even then the challenge takes the form of an appeal of particular claims, and the decision is technically limited to those claims. Thus, as a practical matter, the Supreme Court's holding has been overruled by Congress, and there is no longer an effective means to challenge HCFA coverage policies.

In my view, Congress should consider restoring the right of beneficiaries and other interested parties to obtain judicial review of Medicare regulations and other policies without first going through the administrative law judge process. The Supreme Court unanimously recognized that right in 1986, but Congress implicitly, and perhaps inadvertently, repealed it only a few months later when it enacted the existing appeals mechanism.

Issues Related to Coverage of New Technologies

Although the Committee's focus is on the process for making coverage decisions, I would like to briefly mention two related procedural issues that also bear as a practical matter on coverage of new technologies.

- Issuance of New Codes

Every drug and medical device that is covered by Medicare, and for which separate payment is made, has a billing code under the HCFA Common Procedure Coding System. New codes are issued by HCFA in cooperation with insurance organizations. The policy of HCFA and these other organizations is that an application for a new code is not considered until the product has been on the market for six months. In addition, the cut-off date for consideration of new codes is relatively early in each year for code changes to take effect the following January 1. As a result, if a drug is approved by the Food and Drug Administration on, for example, February 1, 1999, the requirement for six months of marketing experience and the early cut-off date mean that a new code for the drug will not go into effect until January 1, 2001—nearly two years after approval.

Until a specific code for a drug goes into effect, physicians administering the drug must use a non-specific, miscellaneous code and provide additional information about the drug in narrative format on the claim. This means that the claim cannot be processed automatically, and payment to the physician is delayed. Physicians may be reluctant to use new products if they encounter payment delays and more burdensome billing requirements.

The reason that HCFA requires six months marketing experience is apparently the desire to determine whether a new product will result in a sufficient number of Medicare claims to warrant issuing a new code. While this may be a justifiable policy to apply in the case of minor medical devices, which may not be successful in the marketplace, it is unreasonable to apply this policy to new drugs and important medical devices that will plainly generate many thousands of Medicare claims. Indeed, it is unclear why there should be an application process at all for new drugs, in which a committee evaluates whether to issue a new code, since Medicare covers all new non-self-administrable drugs. If HCFA routinely issued a new billing code as soon as it was informed that an injectable drug was being marketed, the cut-off date could be extended much later in each year, and the need for six months marketing history could be eliminated. In the unlikely event that no claims were ever filed for the drug, the code could be deleted at a future time.

• Adjusting DRGs for New Technologies

In the case of drugs, medical devices, and surgical procedures furnished to hospital inpatients, a question that is often more important than coverage is the payment level for the new technology. New procedures are assigned to a diagnosis-related group (DRG) that describes their general circumstances. For example, treatment of brain cancer with a new drug would fall into the DRG for non-surgical treatment of brain cancer, and a hospital using the drug would receive the existing payment amount for that DRG. If that payment amount is not appropriate for the new procedure, HCFA allows for the possibility that the new procedure can be transferred to a different DRG with a more appropriate payment level, or that a wholly new DRG might be created for the new procedure. The HCFA policy, however, is that it will evaluate whether the payment level is appropriate based only on Medicare claims data. Therefore, the new procedure must remain in the initial DRG at least a year or two while claims data are accumulated and analyzed by HCFA.

This rigid insistence on using only Medicare claims data results in delays in setting appropriate payment levels. When payment amounts are significantly less than the costs incurred by hospitals, they may refrain from using the new procedures, to the detriment of Medicare beneficiaries. For example, when Medicare first decided to cover bone marrow transplants for certain conditions, they were assigned to DRGs for the underlying conditions, which had average payment levels of about $5,000 to $10,000. Of course, everyone understood that this amount was far below the actual cost of a bone marrow transplant, but HCFA adhered to its policy of making no changes until actual claims data were collected. Eventually, that data became available, and in 1990 HCFA created a new DRG for bone marrow transplants and assigned it the average payment amount of about $45,000.

While it is understandable that HCFA does not want Medicare to overpay for new procedures, there would seem to be room for the agency to make a conservative estimate of costs and assign new technologies to DRGs that are more likely to represent their true costs. It seems to be poor policy to discourage hospitals from providing life-saving treatments such as bone marrow transplants for leukemia by deliberately setting a payment rate that is far below any fair estimate of the costs involved. Adjustments to refine the payment amount can be made in subsequent years based on actual claims data in the same manner that they are made now.

A related issue is the problem of tracking the use of new drug therapies in hospital claims data. Although new ICD–9–CM codes are assigned to new surgical procedures for hospital billing purposes, they are not assigned to new drug therapies. Accordingly, even after a year or more of actual claims data exists, it may be difficult or impossible to identify the patients who received the new drug therapy. If those patients cannot be identified, it is impossible to determine whether the drug therapy is classified in the appropriate DRG or to move the therapy to a different DRG. It would be desirable if HCFA assigned ICD–9–CM codes to costly drug therapies so that use of the drug therapy could be followed and the DRG adjusted if appropriate.

Conclusion

In summary, there are a number of issues that Congress may wish to consider to improve the Medicare process for coverage decisionmaking and appeals:

• The role of the contractors in deciding coverage policy should be re-examined, since their involvement leads to non-uniform interpretation of Medicare benefits and requirements. To the extent that they continue to make policy, the use of coordinated action by these unaccountable companies to promulgate national coverage policies is highly questionable.

• There should be more openness and opportunity for public participation in national coverage decisions without imposing the Administrative Procedure Act requirements applicable to rulemaking.
• HCFA should issue regulations that clearly and comprehensively set out the criteria for Medicare coverage of items and services.
• Congress should consider reinstating the procedure for direct judicial review of Medicare Part B policies that the Supreme Court established but that was effectively overturned by Congress in the 1986 amendments.
• HCFA should consider a more flexible approach to dealing with issues that in reality affect the introduction of new technologies, such as the issuance of new codes and the assignment of new procedures to appropriate DRGs.
Thank you for the opportunity to present this statement.

Chairman THOMAS. I thank the gentleman. I know that this particular area that we were dealing with was one in which my colleague from California, Mr. Waxman, was heavily involved, and I have a hard time believing that if something was done and if he was involved, it was unintentioned.

Ms. Gottlich.

STATEMENT OF VICKI GOTTLICH, ATTORNEY AT LAW, NATIONAL SENIOR CITIZENS LAW CENTER

Ms. GOTTLICH. Good afternoon, and I want to thank you for the opportunity to come talk before this Subcommittee. The National Senior Citizens Law Center is a nonprofit organization that has advocated for older people and people with disabilities for over 25 years. We have a large network of advocates with whom we converse on Medicare issues, and my comments today reflect a lot of the comments I have received from attorneys and paralegals who do the actual representation of beneficiaries in Medicare cases.

We, too, are very concerned about the national coverage determination process. I have not had the opportunity yet to look at the new proposed rule, but in the fall when HCFA requested comments on the national coverage determination process, NSCLC sent in comments that sound very similar to what is being proposed. We had asked that there be an administrative process so that beneficiaries and other interested individuals could ask for redeterminations of NCDs or could ask for new NCD determinations. It was our hope that in this administrative process we would then be able to go to Federal court. We did not foresee that we would then have to go through the layers of reviews that we have at this time.

We are also heartened that beneficiary representatives will be allowed to be included in the new Medicare Coverage Advisory Committee. We would like to ensure, however, that beneficiaries are adequately represented. We always think of seniors as Medicare beneficiaries, when, in fact, 5 million or more beneficiaries are people with disabilities. And for the younger disabled community, many of them are very adversely affected by national coverage determinations that involve new equipment or new devices. Many of them are very knowledgeable, and their interests need to be represented as well.

The effect of the local coverage determinations can be very harsh on Medicare beneficiaries. While a Medicare beneficiary may be able to benefit from the coverage determination in the area where the service is received, that can be a hardship for individuals, and,

in fact, I have worked with some attorneys whose clients had to disenroll from managed care plans and move to other portions of their States or other portions of the country in order to get coverage of a service that is only approved in a specific part of the country.

One of the problems that we foresee and that the Chairman touched on a little bit is the fact that the Medicare part A and part B process really is a reimbursement process for services that have been received, and in certain instances, beneficiaries who cannot afford to lay out the money for the services are not able to even enter the appeals system. This happens in several situations. It is generally when you are trying to buy assistive devices or durable medical equipment; it happens if you are trying to get skilled nursing home care, and it can happen if you are trying to get home health care. The way the process works in those situations is if the home health agency or the SNF says to you, "We don't think that this is covered. You can pay privately. We will submit a demand bill to the intermediary or the carrier. They will then determine whether or not Medicare will cover this service." If you can't pay out of pocket for this service, then you are foreclosed from ever getting a determination from Medicare whether or not that service should be covered.

We have also found other problems with this situation. Many times, the providers will not submit the demand bills to the intermediary, and in one really egregious case that we know of from Cincinnati, it took 2 years for the home health agency to finally agree to submit the demand bill to the fiscal intermediary. They only did so based on pressure from HCFA, and in the letter from HCFA telling them they had to submit the demand bill, HCFA also told them how to submit the bill so that it would be paid because it was 2 years old and was a stale bill.

One of the other things that we would like would be to have some kind of expedited determination process so that if you cannot afford to get the service, if you cannot afford to get the durable medical equipment, then you can get an opinion from the fiscal intermediary or the carrier issued on a very short basis, 15 days, that this item should be covered.

Notice is a really top issue for us. Adequate notice is what informs people of their right to appeal. For the most part, people do get adequate notice of part A and part B coverage, but there are certain instances where notices are not being provided. The home health industry is one area where notices are not being provided, and people don't know that they have appeal rights. We are in the process of suing HCFA over this issue right now. And I know we are not focusing on HMO appeals, but the GAO report last week about the failure of HMOs to comply with the Balanced Budget Act is really helpful and really bears out everything that we have found.

We have talked about delays, and we concur very heartily in the concern about delays; 2 years for an ALJ hearing is not sufficient. I do want to note, however, that there is a little known process that allows you to get a very, very expedited ALJ hearing, and it is really only if someone is terminally ill. So, there is actually a client that I am working with who got notice from his HMO on January

25 that his service would no longer be covered, and his ALJ hearing is tomorrow. I have never seen that before, and I have been doing this a long time.

The one other issue that we would like to mention is the clarification of the home health appeals process. In the Balanced Budget Act when most of home health benefits were moved to part B, there was some concern about whether the part A or the part B appeals process would apply. The BBA provides that the same appeal rights for beneficiaries under parts A and B apply by changing the amount in controversy for home health claims under part B to $100. We would like to make sure that those claims do not have to go through the part B hearings before they get to the ALJ hearing.

And I guess there is one other comment I would like to make. For us policymakers, we think this process is confusing with all the layers of review. So, if you were to ask me, I would say cut it all out. When I talk to advocates who actually represent clients, their viewpoint is very different. They say that carrier hearings help. They say that review at the fiscal intermediary stage helps and that they often get favorable decisions. They also point out that the part B hearings are very useful where the amount in controversy is under $500, because you then can't get an ALJ hearing. We would suggest that those levels of review be made optional so that you can go straight to the ALJ stage but use those levels of review if your claim is very small.

Thank you.

[The prepared statement follows:]

Statement of Vicki Gottlich, Attorney at Law, National Senior Citizens Law Center

Good afternoon. I am Vicki Gottlich, an attorney with the National Senior Citizens Law Center (NSCLC) in Washington, D.C. NSCLC is a non-profit organization that has advocated for over twenty-five years on behalf of low-income older people and people with disabilities in a variety of areas, including Medicare, Medicaid, and private employer-sponsored health insurance. As part of our Medicare work, we convene monthly teleconference calls with Medicare advocates from across the country to discuss current issues and problems faced by Medicare beneficiaries. We also have a special grant from the National Association of Protection and Advocacy Systems (NAPAS) to provide technical assistance on Medicare issues to advocates for people with disabilities. Issues concerning what is a Medicare covered service and questions about appeals procedures frequently arise in my individual conversations with advocates as well as in the monthly phone calls. I therefore appreciate the opportunity to discuss with the Subcommittee today the issues Medicare advocates have identified and the experiences of beneficiaries.

As the Subcommittee is aware, Medicare is divided into three parts. Part A generally covers hospital and other in-patient services, Part B generally covers doctors services and durable medical equipment, and Part C establishes the Medicare+Choice program. Each part has its own initial appeals process which beneficiaries must exhaust before moving on to a hearing before an administrative law judge (ALJ), then to review by the Department Appeals Board, and then possibly to federal court. In addition, there are special appeals rules for hospital discharge and special notices for discharge from a skilled nursing facility. There are separate procedures for quality of care complaints.

While the list sounds—and is—complicated, the average beneficiary does not experience the confusion about the process that one would think arises from such a convoluted system. Most beneficiaries are not aware of the details of appeals procedures until their claim for payment of a service, procedure or equipment is denied. When that happens, the denial notice sent to the beneficiary by the fiscal intermediary, if it is a claim under Part A, or by the carrier, if it is a claim under Part B, describes the appropriate appeals process for a claim under that part. Similarly, hospital discharge notices given to beneficiaries in advance of their discharge and

"Sarrassat" notices given in advance of discharge from a skilled nursing facility describe the procedures to use in those situations. Thus, beneficiaries are given information on how to file an appeal of that particular kind of claim at the time they need the information.

The fact that beneficiaries should be informed of their rights in the fee-for-service context does not mean that the system is problem free. I will now address several of the main concerns about coverage determinations and appeals procedures raised by beneficiaries and their advocates.

National Coverage Determinations

Beneficiary representatives give great priority to establishment of a mechanism to protect the rights and interests of beneficiaries in the National Coverage Determination (NCDs) process because, under the current NCD process, their clients' rights and interests are not protected. We have considered various remedies, including litigation, to redress the harm suffered by elderly clients and clients with disabilities who are unable to obtain critically needed medical procedures because of NCDs based on scanty evidence, questionable standards, or stale information.

Currently, there are two ways in which the public might theoretically have input into the content of Medicare rules denying coverage of medical procedures. One is by involvement in the Health Care Financing Administration (HCFA) process for enacting NCDs. The second is by raising issues concerning the legitimacy of the NCD during the beneficiary appeal process I described briefly above. For different reasons, these two avenues for input by the consuming public are essentially foreclosed at this time.

Involvement by consumers in the initial HCFA NCD enactment process is very rare. First, few patients know that they will need a medical procedure when the NCD rule making process is underway. Second, even if a patient has timely knowledge of an NCD process that would affect her, she generally lacks resources to participate effectively in the process. Third, as this Subcommittee is well aware, HCFA's Technology Advisory Committee (TAC) did not openly invite participation by Medicare beneficiaries or the general public. There was a lack of clarity about obtaining a NCD for new procedures, devices, etc. outside the context of an appeal.

The appeals process also provides no recourse for beneficiaries. Beneficiaries have been foreclosed from questioning NCDs in the course of coverage appeals by 42 U.S.C. § 1395ff (b) (3). That provision makes it nearly impossible for a beneficiary to challenge the rule upon which services were denied by preventing consideration of the issue at the administrative level. If the claim reaches federal court, a federal judge who determines that the record is incomplete or insufficient to support the validity of the NCD must, under Section 1395ff (b) (3), remand the case for supplementation of the record. The court may only determine that an item or service is covered after review of the supplemented record.

Last fall, HCFA held a Medicare Coverage Town Meeting and published a notice in the Federal Register inviting comments on changes to the NCD process. NSCLC and the Consumer Coalition for Quality Health Care joined in comments filed by the Center for Medicare Advocacy in response to the Town Meeting and Federal Register notice. We suggested to HCFA that the agency create a meaningful opportunity for beneficiaries to question NCDs. The NCD process must be faster and less arcane. We proposed that a process be established to allow a beneficiary who is denied services or payment because of an NCD or who is seeking to establish an NCD to request prompt administrative reconsideration of the NCD. By filing a petition with HCFA, the beneficiary could initiate an administrative review of the NCD that focuses on whether it currently meets the criteria for enactment of NCDs. Such a post-enactment review is particularly necessary for NDCs involving new procedures because new evidence concerning efficacy emerges over time, with HCFA re-evaluation often lagging behind. In order to give legitimacy to this reconsideration process, the beneficiary should have the further right of appeal to federal court.

NSCLC also responded to HCFA's Federal Register request last December for nominations to the new Medicare Coverage Advisory Committee that is being formed to replace the TAC. We nominated two beneficiary representatives who have had experience with the current process. We also encouraged other beneficiary advocates, including advocates who are knowledgeable about assistive devices and other technologies, to apply to serve on the new committee. It is crucial that beneficiaries be adequately represented in any new process developed by HCFA for making NCDs. Adequate representation means inclusion of advocates who represent the interests of the diverse Medicare beneficiary community. We often refer to "seniors" when describing Medicare beneficiaries, yet over 5 million beneficiaries are younger people with disabilities. Many members of this community are adversely impacted

by HCFA's failure to include new devices and technologies among Medicare's covered services. Their voice needs to be heard in any process that reviews and re-evaluates new technologies, services and procedures.

LACK OF APPEAL RIGHTS UNDER FEE-FOR-SERVICE MEDICARE WHERE THE SERVICE HAS NOT ALREADY BEEN RECEIVED.

The current Medicare appeals process under Parts A and B is premised on a delivery model in which beneficiaries obtain a service or procedure and then seek reimbursement. This system adequately meets the needs of beneficiaries who are not waiting for a determination by Medicare before they obtain needed care. Problems arise, however, where the issue is prior authorization of services or items as opposed to reimbursement.

For many low-income beneficiaries, the current system precludes their ability to obtain the equipment and services they need. They cannot afford first to purchase the equipment or receive the service, the initial step in getting Medicare to cover their medical need, and then submit a claim for reimbursement. In the context of Medicare home health services, if the home health agency believes Medicare will no longer cover the service, the beneficiary must pay for the service privately while the agency submits a "demand bill" to the fiscal intermediary. Again, beneficiaries who cannot afford to pay out of pocket have no access to the appeals process to determine whether Medicare will in fact pay for their care.

We have also found that if a home health agency or a skilled nursing facility determines on its own that Medicare will not pay, the agency or facility may deny the beneficiary access to the service by refusing to admit the beneficiary. Where that determination is not correct, the agency or facility's unwillingness to even provide the service precludes the beneficiary from filing a demand bill to get a determination from Medicare about whether the service will be covered. Without such a determination from the fiscal intermediary in these cases, the beneficiary cannot seek an appeal.

Just as beneficiaries enrolled in a Medicare+Choice plan have the opportunity for an expedited appeal when the plan denies a service, beneficiaries in fee-for-service Medicare should have access to an expedited determination that Medicare will pay (or not pay) for the needed device or services. Beneficiaries should be able to request an intermediary or carrier determination, issued within 15 days of the request, that Medicare will cover the equipment or service in question. They can then present the determination to the provider or physician and obtain the item or service in question. If the request is denied, they should have the opportunity to appeal through an expedited appeals process. Such a process will enable individuals who cannot afford to pay out of pocket the opportunity to access the appeals process.

NSCLC is co-counsel in a nationwide class action filed in the United States District Court for Connecticut called Healey v. Shalala. In that case, we are challenging the appeals process as it applies to denials, terminations, and reductions of Medicare home health services. Among the issues raised in the case are the lack of expedited review and the lack of an appeals process for beneficiaries who cannot afford to pay privately for their care. The case provides a good example of the dire consequences to the beneficiary from being deprived of both a service and a process through which to appeal that denial. Within the first few months after the Healey case was filed, two of the named plaintiffs who were denied home health services died.

I mentioned earlier that, where a provider believes that Medicare will not pay for a service and requests the beneficiary to pay out-of-pocket, the beneficiary may request that the provider submit a "demand" bill to the fiscal intermediary (for skilled nursing facility or home health claims) or to the carrier to get a determination of coverage that can then be appealed if unfavorable. We have found, unfortunately, that some providers are unwilling to submit demand bills, thus depriving beneficiaries of the right to pursue their claims with Medicare. In one egregious case from Cincinnati, it took two years to get the provider to submit the demand bill for home health services.

ADEQUATE NOTICE

Appeals processes work only when beneficiaries are informed of their appeal rights. In the fee for service context, as I noted earlier, standard notices explain what those rights are and how beneficiaries may access the review process.

Unfortunately, there are situations in which Medicare beneficiaries are not adequately informed of their right to appeal or, if informed, are not given information that would allow them to begin the appeal process. For example, the Healey case arose because Medicare home health beneficiaries did not receive notice from their

home health agencies that their home health services would be reduced or terminated. If they did receive written notice, the notices often did not explain their right to request a "demand bill" and to file an appeal if the demand bill was rejected. In addition to the other relief in that case, we are seeking that HCFA require home health agencies to give beneficiaries a standard notice that explains what services are being denied, reduced, or terminated, the reasons for the denial, reduction, or termination of services, and the procedures to follow to get a formal determination of Medicare eligibility from the fiscal intermediary.

A GAO report [1] issued last week found that, despite a court ruling and changes made to the Medicare managed care appeals process by the Balanced Budget Act of 1997, Medicare HMOs still are not providing beneficiaries with adequate notice of their appeal rights. The GAO found that notices frequently failed to explain appeal rights and/or did not state the reason for the denial. They often were given with little advance notice of discontinuation of a service such as skilled nursing care, leaving beneficiaries without time to plan how to obtain and pay for the service. The GAO, after reviewing cases sent to the Center for Health Dispute Resolution for review, also noted that some beneficiaries do not receive notices at all.

The GAO's findings comport with the experiences of the Medicare advocates with whom I work across the country. In one case from South Florida, for example, the beneficiary was told orally by her HMO that home health services would stop the next day. She was given no an explanation why they were being terminated and given no explanation of her appeal rights. When the attorney called the HMO on the client's behalf to get more information and to ask for an expedited plan reconsideration, she was told by the plan representative that the client had no appeal rights at all.

We therefore concur with the GAO recommendations that HCFA develop standard notices and increase its oversight, monitoring and enforcement of the Medicare+Choice appeals process. We would extend this recommendation to oversight, monitoring and enforcement of the appeals processes available under other Medicare appeals systems.

Delays in the appeals process

From a policy perspective, the multiple levels of review in the appeals process appear to add confusion and to be somewhat unnecessary. However, in practice, the carrier review and intermediary reconsideration stages sometimes allow for claims to be resolved without the need for ALJ review. According to HCFA statistics, the reversal rate is 76.9% for carrier reviews and 42.9% for intermediary reconsiderations. In addition, carrier review and intermediary reconsideration provide a forum to resolve small disputes that do not meet the jurisdictional limits for ALJ hearings ($100 for Part A claims and $500 for Part B claims). The real problem that arises at this level of review is the length of time it takes to get a carrier or an intermediary determination. Delays can be particularly intolerable where a beneficiary has paid or is paying for a service out of pocket.

Several small changes can address this issue. These levels of review could be made optional for beneficiaries with larger claims who want to proceed directly to an ALJ hearing. Also, carriers and intermediaries should be required to make decisions within 30 days of receipt of the claim. If decisions are not made within that time frame, beneficiaries should be allowed to proceed automatically to the ALJ level, and be notified of this right when they are told of their initial appeal rights.

Similarly, time limitations should be established for ALJ hearings and decisions. We have heard from beneficiary representatives whose clients waiting as long as two years to get an ALJ hearing, and may wait almost as long to get a decision. Again, if time limitations are not adhered to, the beneficiary should be allowed to proceed directly to federal court. There also needs to be a provision for expedited ALJ hearings. The Social Security Administration already has a little known procedure to move a case to the top of the ALJ hearing waiting list in limited circumstances, generally where the claimant is terminally ill. This procedure may need to be broadened and better publicized to protect individuals who would meet the Medicare+Choice criteria for expedited consideration.

Clarification of the home health appeals process

When the Balanced Budget Act of 1997 transferred most of Medicare home health benefits from Part A to Part B, Congress was aware that this change could result

[1] Medicare Managed Care: Greater Oversight Needed to Protect Beneficiary Rights (GAO/HEHS 99–68, April 1999).

in the same beneficiary having some of her home health claims being processed under the Part A process and some of her claims being processed under the Part B process. Thus, the BBA provides the same appeal rights for beneficiaries under Parts A and B, changing the amount in controversy for ALJ review in Part B home health claims from $500 to $100. What is not clear to advocates is whether claims for home health benefits under Part B would be administered completely as if they were claims under Part A. We would like further clarification that all home health claims, whether paid under Part A or Part B, would be administered through the Part A system.

CREATION OF A MEDICARE COURT

Beneficiary advocates have questions about the creation of a special Medicare Court. We are not aware of any data to show that enough Medicare cases are filed to warrant the establishment of a new Article I court. According to HCFA reports, few intermediary reconsiderations and carrier reviews are requested, and the reversal rates, particularly for carrier reviews, are high. While we don't know the number of ALJ hearings requested, we know anecdotally that the number of appeals decreases as beneficiaries progress through the appeals system, and that few federal court cases are brought. Therefore, a first exploratory step before establishment of a new court might be to gather more empirical data about the number of appeals at the ALJ, Departmental Appeals Board, and federal court levels.

We appreciate the efforts of Chairman Thomas and this Subcommittee to support adequate appeal rights for Medicare beneficiaries. We look forward to continuing to work with you on this important issue.

Chairman THOMAS. Thank you very much. All of you gave us excellent testimony. I guess if I were going to be outraged about anything I have heard so far is that this is not 1965; this is 1999; this is an administration that it is in its second 4-year term in which they use a lot of words about being on the side of the beneficiary, and what we heard today from a beneficiary activist, Ms. Gottlich, was that you are very concerned about having access to appeals governed by wealth; that there is a frontloaded process in which some people are not able to participate to get what they believe is justice. If this were in the legal area, that would be outrageous; it is just as outrageous in this area.

But, probably, even worse than that was Dr. Kang's suggestion that because of the differing decisions in various local areas, if you are denied in your region you can go to the other region that offers the service, and you can get it. Well, now who gets to move around the regions? I mean, this is then the wealthy who get to select where they get it if it is available anywhere, and if you are unfortunate to be poor and have to live in an area and you have been denied, you don't get it. Now, that is the kind of inequity that maybe should have been put up with in 1965, but it is just outrageous today, especially when it is the consumer advocate who is complaining about the wealth structure, and it is the representative from HCFA who has given you a way around the system, and oh, by the way, it is only if you are wealthy enough to play the game. That is what I find really outrageous.

Professor Kinney, you touched on the local versus the national, and, again, we heard the argument that somehow this diversity is healthy, and I would just like to go across the panel and ask you if the—have you had a chance to look at the notice that just came out today in terms of the change?

Ms. KINNEY. It was just—I only got it when I came into the hearing room this morning.

Chairman THOMAS. And that is why this is not as useful as I would have liked. I am pleased the administration decided to follow the law. I am disappointed it has taken them so long to give us a product that we can try to evaluate to see if, in fact, it does a better job. We are all anticipating that it does do a better job, but I guess I am a little disappointed based on all the arguments I heard a year ago that they have continued to make the decision that there won't be a process of rationalizing the local in any meaningful way except after what seems to be a very laborious process. Is it a positive on the whole or is probably not a positive any longer that we allow these hundred flowers to blossom until somehow there is this agreement that it ought to be done at the national level? Is that still a useful way to try to deliver services?

Ms. KINNEY. I am not sure it is avoidable. There are a large number of individual cases to be decided nationwide and lots of new treatments and devices being developed all the time. Medicare is now structured to enable decentralized decisionmaking on these money issues by carriers and other contractors. And I am not sure that we could develop as effective a mechanism at the national level to identify all the potential devices, procedures, operations, that call for a specific coverage decision and make appropriate decisions in an expeditious and consistent manner.

On the other hand, I have always been troubled by the "Let a hundred flowers bloom approach." Early in the eighties, for example, Medicare covered heart transplants in California but not in other parts of the country. This has been a persistent problem of the program since its inception. We can do a better job of coordinating the decisions that are made at the local level with what are being made at the national level. For example, HCFA might establish a regional or national office to collect, consolidate, and reconcile these policies. HCFA should establish better mechanisms and criteria for referring issues that call for a national coverage determination. So, while I think that regional variation is probably unavoidable, better coordination policy is possible.

Chairman THOMAS. Yes, at least communication and information transfer between different regions so there could be decisions made based upon fresh information.

Mr. Coleman.

Mr. COLEMAN. My experience is that the lack of uniformity does not stem from some sort of conclusion about the local medical practice. It simply results from the fact that the medical directors in each carrier evaluate the situation differently. They purport to be applying the same criteria; they purport to be looking at the literature or whatever to decide whether or not an MRI scan is useful in a particular procedure, but they come to different conclusions having nothing to do with local medical practices.

Chairman THOMAS. And could you infer from that that maybe this is one of the more effective cost control methods?

Mr. COLEMAN. Certainly. I mean, it depends on the personality of the local medical director. If the local medical director is very conservative and wants to hold down costs, it is not surprising that his coverage decisions tend to be more strict than somewhere else.

Chairman THOMAS. Ms. Gottlich, any comments?

Ms. GOTTLICH. From a cynical viewpoint, sometimes we prefer that the decisions be made on a local level, because then we know that we can appeal them through Federal court, and if they are made on a national level, then they are not subject to Federal court appeal if we don't like them. But I am concerned about the delays in getting the information from one local area to the other; it is the coordination, and then getting the information to HCFA. I don't understand why if the local region is covering something for a long period of time and meets their criterion, why it shouldn't be moved up and everybody get covered.

Chairman THOMAS. Yes, timelines, criteria, number of regions, some kind of a tip that gives you a direction that ought to be followed. And just, finally, Ms. Gottlich, I appreciate your tip in terms of how to expedite the review. I don't know how much comfort it would give me that I found out that I was denied before I died.

Does the gentlewoman from Connecticut wish to inquire?

Mrs. JOHNSON of Connecticut. I just want to be sure—thank you very much for your testimony and when you do see these regulations and have a chance to study them, we would certainly want to know what you think. But, Ms. Gottlich, did I understand you correctly to say that you have seen a situation in which under a managed care choice plan someone got an appeal dealt with in a brief period of time?

Ms. GOTTLICH. Absolutely. I was floored. It is a person with AIDS, and he did the initial appeals himself. He asked for an expedited review. He wrote "I am terminally ill," which, unfortunately, he is, and he went through the appeals process. He is now represented by an attorney; it is a case in New York.

Mrs. JOHNSON of Connecticut. How long did it take him to get to where he is now?

Ms. GOTTLICH. As I said, he got the notice on January 25 that the service would not be covered. So, he went through the plan reconsideration, through CHDR, and now the ALJ hearing is tomorrow, which is——

Mrs. JOHNSON of Connecticut. Now, is this the result of the policy of the managed care plan he participates in?

Ms. GOTTLICH. No, I think that what happened in this particular managed care plan was that they actually followed the rules. We have had lots of situations in managed care plans that don't follow the rules, and, unfortunately, some Medicare HMOs are still saying there are no appeal rights, which is unconscionable. But, anyway, they followed the rules. So, they——

Mrs. JOHNSON of Connecticut. So, in other words, Medicare has actually set up good rules if we can enforce them for managed care choice plans.

Ms. GOTTLICH. That is right.

Mrs. JOHNSON of Connecticut. And, in fact, participants in managed care choice plans have superior appeal rights to Medicare participants in fee-for-service.

Ms. GOTTLICH. Oh, no question.

Mrs. JOHNSON of Connecticut. I am truly, absolutely appalled at the lack of any rights of the fee-for-service participants in managed care, and your comments earlier on the value of the local process and the more earlier levels of setting and educating everybody in-

volved were very interesting to me. How we draw from that and have a more responsive relationship between the local processes and the Federal process so there is more uniformity is really a concern to me. I cannot get an adequate estimate about how much it will cost us to include seniors in clinical trials, because, frankly, some of the local groups are already including them, but they don't want to call it that. They sort of don't want to own up because then it makes them stick out. So, they are just not saying it is clinical trials; they are just providing whatever health care sees. So, we can't get estimates, because we don't have a policy here. So, we are literally denying seniors, many seniors, the right to participate in clinical trials while many seniors have the right to participate in clinical trials, and the system has absorbed that cost if, indeed, there is any. So, this is a very big problem, and, ironically, any managed care plan that is going to grow big in the private sector has to have an MCQA certification, and that provides a lot more visibility than a lot of these coverage decisions that we are providing now in the public programs. Thank you very much for your testimony.

Chairman THOMAS. Does the gentlewoman from Florida wish to inquire?

Mrs. THURMAN. I really don't, and I am sorry I missed your testimony. I just like to say, Ms. Kinney, I am interested at some time you have made a lot of recommendations in how you think you might streamline. I hope that maybe sometime, Mr. Chairman, we will have an opportunity to better look at that; maybe even get more testimony from that. And the only other thing I would say is that it looks like this has been going on for a long time, not just short period of time.

Chairman THOMAS. It is, and I will tell the gentlewoman that it came to a head, because we finally got them to admit that what they were doing was against the statute, and I guess I am a little underwhelmed at the more than a year review of what would resolve it in terms of opening up the process, and I just thought that since a number of these areas had been looked at for some time, that we would see some tweaks along the line to improve both on a timeline and on a cleaning up of all those lines crossing. So, I am little more disappointed in the proposed work product than I wanted to be.

Mrs. THURMAN. And I don't disagree with that, and I think that all of the things that have been mentioned here today, particularly to those that are being covered by this, on the other side of this, I know that we have also made a lot of changes in the law, and, as we heard just a couple of weeks ago or months ago about the 300 changes that have been going on, that is quite a bit of a responsibility too.

Chairman THOMAS. Which leads me to my next question, and I would like you folks to respond to it. I don't like to spend money unless we have to, because it is not my money; it is other people's money. But, periodically, as areas have gotten more complex and decisions are more and more required to be made in a context of expert and particular knowledge, we have created courts under article 1 of the Constitution instead of the judicial branch article that are called legislative courts—tax court of the United States in

terms of the complexities of the tax law. Do you believe we have reached a point or that it is overdue that we create, in essence, a Medicare court, a legislative court, rather than relying on the hit and miss choice in the administrative law justices from the Social Security Administration; that we talk about people who are going to render decisions in this area who are knowledgeable in the law who understand it, and who, through a collection of decisions, build a degree of what the constitutional courts would call state of decisis, so that you can maybe speed up the process by having courts dedicated to this decisionmaking process? Is Medicare adult enough to require its own court, I guess is what I am saying?

Ms. KINNEY. Well, I think the Medicare court idea is an intriguing idea. One of the concerns you have is whether the decisionmakers on the court could be "captured," if you will, by the bureaucracy. By this I mean, over time, their thinking would become too aligned with the program and out of touch with the concerns of beneficiaries. A benefit of the general jurisdiction courts has been their ability to take a fresh look at issues. I do think it is important to make sure that the right issues come before the court and that policy issues like the national coverage determinations probably should stay with the agency—that is, HCFA— which is accountable for the money spent by Medicare and also the safety of the beneficiaries. Further, I am not sure that a Medicare court would be any better to adjudicate the validity of those policies than the Federal judiciary now. But, I think it is an idea that it is intriguing in terms of simplification. I would also like to see the courts try to experiment with alternative dispute resolution techniques and other ways to deal with beneficiary disputes.

Chairman THOMAS. Thank you, because I really haven't made up my mind, and I am trying to see where the evidence falls. Mr. Coleman, do you have a comment on that at all?

Mr. COLEMAN. My comment, I guess, would be that the most complicated issues in Medicare relate to cost reimbursement, and those are the issues that go through the Provider Reimbursement Review Board and then into the courts. Cost reimbursement is being phased out, as you know, so that body of cases—which I think is the most complicated body of cases—will eventually go away, hopefully. And to the extent that more and more Medicare beneficiaries move into managed care, it will diminish further. So, it is a kind of need which may be diminishing rather than increasing.

Ms. GOTTLICH. I have practical considerations. Where would the court be located? How would clients who are homebound or in nursing homes get to the court? If it is in Washington, DC, how would legal services attorneys from Alaska and Hawaii or even southern Maryland or southern Virginia afford to get up here? So, those are my practical concerns.

Chairman THOMAS. Thank you, and, of course, if we are successful in implementing a premium support model, a lot of these particular decisions would be negotiated in a way which would resolve many of them faster, more expeditiously, and between competing interests in the marketplace. But, I am looking at ways to try to straighten that process out, and I appreciate your input in that regard.

If there are no further questions, I want to thank you very much for your testimony, and, as the gentlewoman from Connecticut said, if you will be filing comments on this notice, we would very much like to get them, and if you don't go to the filing stage, we would like your comments anyway.

[The following was subsequently received:]

Memo

To: Subcommittee on Health, House Committee on Ways and Means
United States Congress

From: Eleanor D. Kinney, J.D., M.P.H.
Samuel R. Rosen Professor of Law &
Co-Director, The Center for Law and Health
Indiana University School of Law—Indianapolis
Indianapolis, IN

Subject: Supplemental Statement on Medicare Coverage Decisions and Beneficiary Appeals

Date: October 21, 1999

In the April 22, 1999 hearings of the Subcommittee on Health, House Committee on Ways and Means, Chairman Thomas offered witnesses an opportunity to submit additional comments for the record on the recent Notice of the Health Care Financing Administration (HCFA) on Procedures for Making National Coverage Decisions (the Notice).[1] Below are my comments on the Notice.

INTRODUCTORY COMMENTS

The coverage policy making procedures described in the Notice are, in general, well conceived and designed to facilitate fair and expeditious decision making on difficult questions of Medicare coverage of new and existing medical items and services including medical technologies. The Notice is clearly written and describes an open process that accords all interested parties clear guidance on how to participate in the Medicare coverage decision making process.

HCFA is also to be commended for the innovative use of the Internet in the publication and docketing aspects of the coverage decision making process. It is also useful to permit electronic filing of comments regarding anticipated coverage decisions as this opportunity facilitates the participation of Medicare beneficiaries and physicians in formulating Medicare coverage policy.

I have three major concerns with the Notice: (1) its promulgation as a procedural rule and the resulting appearance that HCFA's commitment to the process is uncertain, (2) the representation of beneficiaries in the process, and (3) the wisdom of allowing local Medicare contractors to supplement national coverage decisions.

1. *Promulgation as a Procedural Rule*

The most important objective HCFA should accomplish with this Notice is to establish a process that has the reputation for integrity and effectiveness among Medicare beneficiaries and the other parties, namely medical providers as well as medical device manufacturers, with a direct professional or business interest in specific Medicare coverage issues. However, the Notice seems inconsistent with this key objective in several respects.

Specifically, HCFA justifies its decision to promulgate the Notice as a procedural rather than legislative rule[2] in an unfortunate way (pp. 22,621–22). Specifically, HCFA refers to the coverage decision making process as an "internal operation." It does seems odd to characterize this process, which has a major impact on many Medicare beneficiaries and their providers as well as the manufacturers of new medical technologies, as "internal." Further, the justification for procedural rules, e.g., according an agency "latitude in organizing its internal operations," does not really fit the coverage policy making process in which there is great public interest.

Perhaps more important, HCFA does not really commit itself to firm deadlines or timeframes in the coverage decision making process. For example, in Section E, "Additional Factors Affecting Our 90-Day Timeframe for Responding to Formal Re-

[1] Health Care Financing Administration, Notice, Medicare Program; Procedures for making National Coverage Decisions, 64 Fed. Reg. 22,619 (April 27, 1999).

[2] 5 U.S.C. 553(b)(3)(A) (exempting "rules of agency organization, procedure, or practice" from notice-and-comment rulemaking).

quests," HCFA suggests that many factors justify extensions of decision making timeframes. While such extensions for the listed reason may be appropriate as a practical matter, such flexibility with timeframes gives the impression that they are effectively voluntary from HCFA's perspective. HCFA may want to consider revisiting the timeframes in the Notice and making them more firm once HCFA has more experience with the process under the Notice.

Ultimately, the reputation of the Medicare coverage decision making process depends on its implementation and operation. Thus, HCFA should make every effort to ensure that the process is implemented and operated with integrity. Specifically, HCFA should meets deadlines and timeframes except in extraordinary and understandable circumstances. Further, HCFA should state requirements for achieving affirmative coverage decisions in the process clearly and explain reasons for negative coverage decisions adequately.

In the future, HCFA might consider promulgating a legislative rule through notice-and-comment rulemaking to establish the elements of the Medicare coverage decision making process. This step would greatly enhance the reputation of the process for integrity, effectiveness and fairness and would also confirm HCFA's commitment to the process. A process with such a reputation would engender confidence in HCFA's decisions on Medicare coverage issues and, hopefully, reduce appeals generated by medical device manufacturers of the type that now occur in the Medicare beneficiary appeals process or in judicial challenges. Finally, a coverage policy making process with a strong reputation is crucial to meet the challenges posed by the advances in costly new medical technologies now and in the future.

2. *Representation of Beneficiaries in the Process*

One of the strongest aspects of the Notice is HCFA's commitment to facilitating the input of Medicare beneficiaries in making coverage decisions. In its section on "Informal Contacts" (p. 22,621), HCFA will assume the responsibility of "gathering and preparing the information necessary to proceed to a formal request" when requests are made by "a Medicare beneficiary or another member of the public who we could not reasonably expect to have access to scientific data that may be necessary to support a formal request." This is an excellent strategy which shows HCFA's thoughtful regard for the barriers to beneficiaries in coverage policy making.

The problem of obtaining adequate input from beneficiaries in the coverage policy making process is very difficult. Beneficiaries, as a general rule, do not have the requisite medical expertise or financial resources to participate in the policy making process in a meaningful manner. Further, unless individual beneficiaries have a particular need for a particular item or service, they are unlikely to participate actively in decision making with respect to specific coverage issues. Further organizations that customarily represent beneficiary interests are not generally well versed in medical matters.

Ostensibly, under liberal administrative law theory, the agency represents the public in a regulatory process. The agency, as the delegate of the elected legislature, must execute the directives of the public's duly elected representatives. In that regard, HCFA should continue to emphasize its role as the advocate for Medicare beneficiaries in the coverage decision making process.

In addition, HCFA might explore other strategies that will enhance effective beneficiary representation in the coverage decision making process. For example, HCFA might consider appointing physicians and others with relevant medical expertise to the Medicare Coverage Advisory Committee with the specific mandate to represent the interest of beneficiaries. That appointee might have the specific charge to work with beneficiaries and interest groups representing their interests in marshaling beneficiary input on specific coverage decisions. HCFA might visibly allocate staff to this effort as well.

3. *Allowing Medicare Contractors to Supplement National Coverage Decisions*

Medicare contractors are authorized to make "local medical review policies" (LMRP) that govern Medicare coverage in the absence of other guidance from the national office. In the Notice, HCFA clarifies that Medicare contracts must follow national coverage determinations and that LMRPs must be consistent with these policies. However, the Notice also indicates that a Medicare contractor "may, however, make an LMRP that supplements a national coverage decision." (p. 22,621).

This later option seems unwise. If an issue were worthy of a national coverage decision, then HCFA has made a judgment that there should be consistency in coverage throughout the United States. However, allowing local Medicare contractors to augment national coverage policies dilutes their uniform and consistent national character. This result could be quite troubling for some providers as well as medical

manufacturers that operate nationwide. In sum, where HCFA has determined that an issue is of national import, national consistency should be promoted.

BENNETT, TURNER & COLEMAN, LLP
WASHINGTON, D.C. 20006
October 7, 1999

The Honorable William M. Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Thomas:

At the Health Subcommittee's April 22, 1999 hearing on Medicare coverage decisions and beneficiary appeals, you invited me and other members of the witness panels to submit comments regarding the revised procedures established by the Health Care Financing Administration (HCFA) for making national coverage decisions. Those procedures were published in the Federal Register of April 27, 1999.

From my standpoint, the principal elements of the new procedures are:

- Establishment of internal timeframes for the various steps in HCFA's process of making a national coverage decision;
- Definition of the required contents of a formal request to HCFA for a national coverage decision;
- A commitment to post information on the HCFA Internet site so that the public can determine what coverage decisions HCFA is considering and where HCFA stands in the process; and
- The use of a Medicare Coverage Advisory Committee to consider issues referred to it by HCFA.

Although these actions are clearly improvements in HCFA's process, the changes are nevertheless quite modest and fall far short of addressing all the deficiencies of the current process. The thrust of the changes is to introduce greater openness into the HCFA process of making coverage decisions, which had been essentially secret. This is a welcome development. In addition, establishing a formal procedure to ask for a national coverage decision will undoubtedly be useful to many affected by the Medicare program.

The new procedures, however, do not deal with some of the greatest needs relating to the coverage process, including:

- Establishing clear criteria for what Medicare considers a medically necessary service that will govern both HCFA and its contractors;
- Improving the process for public input into local coverage decisions made by Medicare intermediaries and carriers; and
- Creating an effective appeals mechanism by which coverage decisions made at the national and the local levels can be challenged.

These issues should be addressed by HCFA or the Congress.

As to the new procedures that HCFA has adopted, in my view the main shortcomings relate to the deadlines for action on national coverage decisions, which are not very demanding. Although HCFA has stated that it will act on formal requests for coverage decisions within 90 days, the action at the end of that period may be merely a decision to ask for a technology assessment by an outside entity, to refer the issue to the Medicare Coverage Advisory Committee, or to do nothing at all and leave the issue to the local Medicare contractors. If an issue is referred to an outside entity for a technology assessment, there is no firm deadline for the assessment and the notice does not appear to establish a timeframe in which HCFA will act following receipt of the assessment.

If HCFA makes a decision in favor of coverage, implementation would not be immediate. HCFA states that generally national coverage decisions would be made effective within 180 days after the first day of the next full calendar quarter following the decision. For example, if HCFA makes a national coverage decision on February 1, it would go into effect by September 30. The notice attempts to justify this extraordinary delay as necessary for administrative changes such as adoption of billing codes and making systems changes at the contractors.

The potentially lengthy periods of time in which HCFA may consider whether to extend coverage to a new procedure or technology, and the subsequent delay in implementation of a decision favoring coverage, seem unduly prolonged. During these

periods Medicare contractors may continue denying Medicare beneficiaries access to a new procedure or technology—even for months after HCFA has decided that it should be covered.

Thank you for the opportunity to submit these comments.

Sincerely yours,

TERRY COLEMAN

NATIONAL SENIOR CITIZENS LAW CENTER
Washington, DC 20005

Chairman William Thomas
Subcommittee on Health
House Committee on Ways and Means
Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Thomas:

You asked the witnesses at the April 22, 1999, hearing on Medicare appeals to submit to you our comments on the new HCFA National Coverage Determination (NCD) process. Please accept this letter as my response to your request.

HCFA's new procedure, which was published in the Federal Register on April 27, 1999, accomplishes various goals. The procedure (1) details several situations which will initiate HCFA's review process for making a national coverage decision;(2) describes the process for requesting a new NCD or review of an existing NCD; (3) establishes time frames for acting on a formal request; (4) establishes a process for posting the status of formal requests that are under investigation on the HCFA web site; and (5) establishes a Medicare Coverage Advisory Committee to review requests and recommend to HCFA whether services are "reasonable and necessary."

The new procedure will make some improvements in the NCD system by creating guidelines and adding more openness and public in-put into the process. To assist beneficiaries who request an NCD, HCFA reserves the discretion to treat informal contacts from individuals or organizations as formal requests, and may in some cases gather and prepare the information necessary to proceed to a formal request. I am also pleased to report that Sally Hart, Esq., a consumer advocate nominated by the National Senior Citizens Law Center, was appointed to serve on the Medicare Coverage Advisory Committee.

Nevertheless, HCFA's procedure does not address two of the major concerns I raised in my initial testimony. The process still involves a substantial amount of delay. HCFA "intends" to make decisions on formal requests within 90 days but acknowledges that this deadline may not be met in a number of cases. If the issue is complex and controversial and potentially a technology assessment, the formal request may be referred to the Medicare Coverage Advisory Committee, which meets only twice a year. Any additional information discovered or submitted during the consideration period will restart the tolling of the 90 day period. And the 90 day clock does not even begin to run until after a request for an NCD is designated a formal request. Especially where consumers ask HCFA for an NCD, the request can languish for an indefinite period of time in the informal stage while sufficient evidence is gathered to transform it into a formal request.

HCFA also does not address our primary concern, the lack of an adequate appeals process when Medicare coverage is denied based on an out-of-date NCD or because HCFA has not yet determined whether Medicare will cover a new service or technology. The Notice fails to outline a meaningful process for beneficiaries to question NCDs. As I explained in my testimony before the Subcommittee, beneficiaries are left with virtually no recourse other than to request a formal determination by HCFA. The onerous NCD process makes it unlikely that many beneficiaries who need a particular service or technology will submit a formal request and that, if a request is submitted, it will be processed in a timely enough manner to benefit the requesting beneficiary.

Thank you for your continuing interest in improving the Medicare appeals process for beneficiaries.

Sincerely,

VICKI GOTTLICH, ESQ.

Chairman THOMAS. Thank you very much.

And if I could now call up the third panel. On the third panel, this is an example rather than abstract or third party. These are individuals who have direct, personal experience with the coverage process.

The first witness will be Walter M. Rosebrough, who is chief executive officer of the Hill-Rom Company in Indiana, and he will be representing in his official capacity the Health Industry Manufacturers Association; some of those individuals who have come up with a lot of these new, innovative medical technologies.

The second panel member is Frank Kiesner—if that is correct—chief executive officer of Oncotech Incorporated, and they are very cutting edge in dealing with cancer patients.

And then our third witness will be Dr. William Plested, who is a thoracic and cardiovascular surgeon, and he will be representing the American Medical Association and will provide us with some of the virtues and vices of the current system from a physician's perspective.

Any written testimony you may have will be made a part of the record, and, Mr. Rosebrough, we will begin with you, and then we will simply move along the panel.

STATEMENT OF WALTER M. ROSEBROUGH, JR., PRESIDENT AND CHIEF EXECUTIVE OFFICER, HILL-ROM COMPANY, BATESVILLE, INDIANA; AND MEMBER, BOARD OF DIRECTORS, HEALTH INDUSTRY MANUFACTURERS ASSOCIATION

Mr. ROSEBROUGH. Thank you, Mr. Chairman. I am testifying today on behalf of HIMA, the Health Industry Manufacturers Association, on whose board of directors I also serve. HIMA strongly supports efforts to improve the Medicare appeals process. My written testimony, which has been provided to you, suggests some our suggestions in detail, but in the few minutes today that I have, I would like to share my own company's difficulty in getting Medicare payments for some of our therapeutic products, specifically, the Clinitron bed and the frustrations we have had dealing with the Medicare appeals process.

The Clinitron used a technology called air-fluidized therapy to treat patients that have extremely compromised skin. Classic examples of these type of patients are burn patients or patients with severe ulcers. As hard as it is to believe, pressure ulcers or bed sores can get so bad, you can literally see the bones of the patients. They are life-threatening, chronic wounds. In effect, the Clinitron makes these patients float as though they were suspended in a fluid which reduces the pressure and friction on the skin which enhances the healing process. This technology is used in hospitals and nursing homes as well as in home care in North America, Europe, Japan, and throughout the world.

In 1990, we applied for and HCFA issued a national coverage decision approving this technology for a specific population of very severe wounds in home care after extensive proof of both clinical and cost effectiveness. Since then, however, the agency's DMERCs, durable medical equipment regional carriers, have denied the major-

ity of claims for reimbursement for this treatment. These denials are disturbing and in our opinion directly contrary to the national coverage decision. As a result, we have had to appeal these decisions to administrative law judges on a case-by-case basis to overturn the DMERC decisions.

I want to emphasize that in thousands of cases brought to the administrative law judges, or ALJ, over the 9-year period since the approved national coverage, the judges have overturned the DMERC rejections in over 95 percent of the cases; over 95 percent of the cases, ALJ has overturned those decisions. In fact, in most cases, the DMERCs don't even show up for hearings anymore.

On the one hand, Mr. Chairman, we are very pleased by the overwhelming success rate at ALJ. On the other hand, we are deeply troubled. Despite the remarkable consistent record of ALJ overturning the DMERCs and despite the tremendous efforts we put forth to work with the DMERCs, they have done virtually nothing to change their policies of denying the initial claims for the Clinitron. In fact, for the most recent 6-month period, they have denied about 80 percent of the requests for reimbursement. From this, it is very clear to us that the appeals process has done absolutely nothing to resolve the fundamental dispute of the regional DMERC policies that we believe are inconsistent with the HCFA national policy.

Our second major concern is that this system of case-by-case adjudication just takes too long. HCFA data show that in fiscal 1997, on average, for part B carrier claims, it took 119 days, about 4 months, for a beneficiary to get through the carrier review and fair hearing steps. When this is added to the other steps in the process, it takes us for our process, overall, an average of more than 2 years to obtain a decision from ALJ on coverage. My wife and I had two children in approximately that same time period, and that is even with an affirmative national coverage decision. From a manufacturers perspective, Mr. Chairman, I can tell you personally that the kind of experience we have gone through to secure our Medicare coverage has been discouraging. But from a patient's perspective and for those physicians who write the orders for those products, I believe it is doubly discouraging.

How many therapies are denied to needy patients because of this bureaucracy? I have no idea. How confusing is it to the patient when they get their copay bill 2 years after they have received the therapy? How many providers can afford to take the risk and a capital cost of 2-year receivables? To have one level of the agency say yes and a lower level of the agency say no and then to wait 2 years to get a final answer, in my view, is simply ridiculous.

In the short time I have left, Mr. Chairman, let me just list a handful of suggestions that we think are most critical to address these problems. First, Congress should require HCFA to create a clear, understandable appeals process for local coverage policy decisions. Currently, none exists. Only the claim-by-claim adjudication that is in our case may never resolve the real policy issue; it is only claim by claim. Second, Congress should confirm that manufacturers of medical products have standing as agreed parties in coverage decisions and appeals. This would let us bring forward in a single appeal the policy issues in question rather than requiring individ-

ual beneficiaries to bring, perhaps, thousands of individual claims which may never resolve the central issue. By the way, as an aside, it would be much more efficient and might require much less money than we have been talking about today in adjudicating those appeals. Third, Congress should require HCFA and its contractors to meet reasonable, commonsense timeframes for appeals. Any process or review that takes 2 years is inefficient and totally unacceptable.

As I said, Mr. Chairman, my written testimony contains additional recommendations and details. I will be happy to answer any questions you or other panelists may have.

[The prepared statement follows:]

Statement of Walter M. Rosebrough, Jr., President and Chief Executive Officer, Hill-Rom Company, Batesville, Indiana; and Member, Board of Directors, Health Industry Manufacturers Association

SUMMARY

My name is Walt Rosebrough. I am the President of Hill-Rom, Inc., a manufacturer of patient care systems, including hospital beds, located in Batesville, Indiana. I am testifying today on behalf of the Health Industry Manufacturers Association—known as HIMA—on whose Board of Directors I serve. Accompanying me is Brad Thompson, a partner in the law firm of Baker & Daniels and counsel to HIMA.

In my remarks today, I want to leave you with the following five points:

- While the Health Care Financing Administration, or HCFA, is working hard to reform the process by which it makes coverage decisions and deserves much praise, there remain important issues such as the need for early collaborative meetings between the agency and manufacturers that continue to be unresolved.
- One of those unresolved issues—the need for an effective appeals process—is critically important to ensuring that the agency is accountable for the coverage decisions it makes.
- Our experience at Hill-Rom with the CLINITRON® bed shows that the current appeals process is ineffective at resolving policy disputes at the local level, and moves far too slowly to meet the needs of beneficiaries.
- There are several statutory improvements that Congress can make to the appeals process, including creating an appeals mechanism for policy issues at the local level and adding the opportunity for administrative review of national coverage decisions. These steps will more efficiently and effectively resolve coverage disputes.
- HCFA, as a government agency that regulates the access to care by seniors, should not be exempt from the need to offer an effective appeal mechanism.

Before I begin, Mr. Chairman, I want to say a special thanks to you personally and to the Subcommittee for the instrumental role you have played in bringing about needed improvements in the Medicare coverage process. There is no question that HCFA's efforts to modernize coverage—to make it more open, timely, and predictable—are due, to no small degree, to your continuing efforts.

DEVICE INDUSTRY PROPOSED REFORMS OF MEDICARE'S TECHNOLOGY POLICIES

To assist HCFA in its task of reforming Medicare coverage, HIMA in mid–1998 developed a range of recommendations for specific improvements to the system. They are described in HIMA's paper entitled "Modernizing the Medicare Coverage Process: A Prescription for Fundamental Reform of Medicare's Technology Policies." Copies have been submitted to the Subcommittee.

Earlier this year, HIMA also participated in the work of a broad group of medical device industry representatives that developed consensus policy positions on the procedural elements of Medicare coverage decision-making. That consensus paper was delivered to HCFA in January. The same group is now set to tackle the substantive criteria that HCFA should use to evaluate technology for possible coverage.

Recommended Coverage Process Reforms

One of the most significant improvements to the coverage process that HIMA and the industry recommend is the need for HCFA to use a notice-and-comment type approach to collecting data and other useful information on proposed coverage policies. While we are certainly not advocating that HCFA follow rule-making in reaching individual coverage decisions, we do think it is critical that HCFA use the Inter-

net and other economical avenues to reach out to a broad public audience to collect information on coverage issues.

In addition, the device industry recommends that HCFA ensure openness in the process for initiating coverage decision-making and in the process for requesting a technology assessment. We also think HFCA should offer manufacturers and others the opportunity to request an early meeting with the agency to reach agreement on the type of information necessary for HCFA to make a coverage determination.

These collaborative meetings might take place well before the start of the coverage process. Not only would such meetings improve the quality of the data presented to the agency, the meetings would add greater certainty to the process from the company's standpoint.

Procedural Reforms Should Be Codified in a Rule

As you know, Mr. Chairman, the controversy over the coverage process has been alive for well over ten years. To achieve the necessary accountability, obtain broad public input on the design of the coverage process, and resolve these issues in an enduring fashion, we believe the agency needs to put these concepts in a binding rule. Unfortunately, the agency so far has opted instead for an informal notice of the kind it published in 1987. We hope it will reconsider that decision.

Agency Progress To Date

The good news is that the agency—with your strong support and oversight, Mr. Chairman—is already making significant efforts to reform the coverage process. After talking with many of the stakeholders and holding a town hall meeting last September, HCFA has re-chartered its technology advisory committee to make it compliant with the Federal Advisory Committee Act. HCFA has also shed some light on the basis for its recent coverage decisions, and I believe it is working on some guidance in a couple of areas. In addition, HCFA appears willing to discuss some issues—such as timeframes—that are so important to ensuring timely access to care. Dr. Kang has made a tremendous effort to have a dialogue with stakeholders, and we hope the current spirit of cooperation continues on all sides.

Effective Appeals Process Essential in Making Coverage Process Work

HCFA has not embraced all of the stakeholders' suggestions. One area of contention is the need to reform the appeals process. A significant part of the industry consensus paper was devoted to describing improvements that are needed in the system of Medicare appeals. Having an effective appeals process for a government agency such as HCFA is absolutely essential to ensure the proper level of accountability.

Appeals are necessary when an agency, for whatever reason, departs from a legal standard—whether that standard is the process the agency needs to follow or the criteria the agency is supposed to apply. Judicial and administrative appeals are not intended to allow stakeholders to overturn an agency decision when reasonable minds simply differ. The agency's decisions are entitled to deference. Even so, the mere existence of an effective appeals mechanism creates an environment in which the agency listens more closely to the public's concerns.

Current Appeals System does not Resolve Coverage Disputes Effectively or Promptly

While an effective appeals system is essential to ensuring appropriate coverage decisions, the current system unfortunately has several deficiencies. I would like to describe for you what we at Hill-Rom see with respect to how the current appeals system handles issues surrounding coverage of one of our products—the CLINITRON AT•HOME® Air Fluidized Therapy Unit—or more commonly known as the CLINITRON Bed.

Background on the CLINITRON Bed

The CLINITRON bed uses a technology called "air fluidized therapy," or AFT, to treat a variety of very sick patients. These patients include, for example, severe burn victims and those with severe pressure ulcers that don't respond to other therapies. Very basically, AFT involves tiny silicon beads that are placed in motion beneath the patient by gentle air flow. The light air flow through the beads "floats" the patient resulting in reduced pressure on the patient's body. The reduction of pressure and accompanying elimination of shear and friction to the skin enhance healing and help prevent further tissue damage.

We developed the product in the 1970s. Numerous studies were conducted which reinforced the clinical efficacy of AFT. In 1987, the Public Health Service developed

consensus guidelines for the proper use of AFT at home, with input from health professional societies and patient groups. By 1990, enough data existed that, after extensive study, HCFA issued an affirmative national coverage decision delineating the patients who could benefit from this therapy at home. That policy can be found in section 60–19 of the Medicare Coverage Issues Manual. As you well know, HCFA deliberates carefully before issuing national coverage determinations, and not many technologies have met that standard.

One would have thought that our story would end there. It did not.

To be quite blunt, the Durable Medical Equipment Regional Carriers, or DMERCs, did not embrace HCFA's decision. As best we can determine, they simply did not agree with the HCFA physicians and scientists on the usefulness of the technology and have sought to add their own definition of medical necessity that is inconsistent with the national policy. As a result, we estimate that the DMERCs have denied close to 80 percent of all claims for reimbursement of the CLINITRON bed presented to them since the national policy was published in 1990.

Appeals of AFT Claim Denials

While those denials have dissuaded some doctors and patients from seeking this treatment, many others, indeed thousands of beneficiaries with the severe injuries identified in the national policy, have sought to obtain access to AFT—despite the opposition from the DMERCs.

The appeals process for these denials involves five steps. In sequence, they are (1) a paper review by the carrier, (2) a "fair hearing" by a carrier hearing officer, (3) a hearing before an administrative law judge, (4) an appeal to the departmental appeals board, and (5) if necessary, an appeal to a U.S. court. Because of the tremendous time, inconvenience, and cost of such appeals, we have helped our elderly patients by accepting assignment of their claims, and have kept track of the results.

In the literally thousands of AFT appeals to administrative law judges since 1990, the beneficiaries have been successful in overturning the carrier decisions in more than 95 percent of the cases.

What the AFT Experience Tells Us About the Appeals System

On the one hand, that success rate is the good news about the system. With an obviously strong case seeking the enforcement of a national coverage decision, the beneficiaries are successful in over 95 percent of the AFT cases.

But in two very real ways, this example shows the system also fails. First, incredibly the initial denial of claims continues after nine years of the DMERCs losing thousands of appeals and after numerous meetings between the DMERCs and Hill-Rom. For the most recent 6-month period, the average denial rate for AFT by the four DMERCs is still over 80 percent. The appeals process has done nothing to resolve the fundamental dispute over the local DMERC policies that are inconsistent with HCFA's national policy.

Second, the system simply takes too long to effectively resolve even the claim-specific disputes. Data obtained from HCFA show that, in fiscal 1997, on average for a part B carrier claim, it took 119 days for a beneficiary to get through the carrier review and fair hearing. HCFA has previously testified before Congress that it takes 664 days, on average, to receive a decision from an administrative law judge, measured from the date the hearing is requested. Thus, combined, it takes an elderly patient on average 783 days, or well over two years, to obtain a decision from an ALJ after initiating the appeals process. That is simply too long to be an effective option for most beneficiaries. Moreover, most small medical device companies could not afford to take assignment of claims in these circumstances, and survive long enough to get paid.

Congress Should Make Improvements in the Medicare Appeals Process

In our experience, as well as the experience of others who have worked with the Medicare appeals process, there are several improvements that Congress can make.

Permit Appeals From Local Policy Decisions

While the current law allows judicial appeals from national coverage decisions (albeit through a seriously flawed process), unfortunately there is no appeals process at all for local coverage policy decisions. Rather, we must rely on a system that forces each beneficiary to appeal individual claim denials on a claim-by-claim basis. When broad principles are in dispute at the local level, Congress should allow aggrieved parties to challenge the broad principle at issue, rather than force an inefficient claim-by-claim adjudication that, as in our case, may never resolve the real dispute.

Medical device innovation is unique in the medical field, and is characterized by continuous, incremental improvements, based on the feedback of professionals who use these technologies in actual clinical settings. The local coverage process is especially well suited to evaluating innovative medical technology, and should remain essentially intact. Thus, while we recommend reforming the appeals process at the local and national levels, we start from the important premise that the present ratio of local to national decisions serves the system well. The current emphasis on local decision-making offers important flexibility that needs to be preserved, is more economical to administer, and helps to ensure that new technology does not diffuse until it is well-accepted.

Create Reasonable Timeframes for Appeals

As I explained above, the appeals process simply takes too long to complete. While this is obviously a function of resources, the decision-makers in the appeals process also need to understand the importance of timely decisions. Statutory timeframes would communicate the Congressional expectation regarding the promptness with which these appeals should be resolved.

Require Finality of Policy Decisions

In many instances, HCFA and the DMERCs deliberate on coverage issues for years. Because there are no final decisions during the time of that deliberation, any appeal is effectively foreclosed, even at the national level.

For an appeals mechanism to create the proper level of accountability, there must be some way to require HCFA and its local contractors to reach decisions that would then be subject to appeal. To be sure, these decisions do not need to be a "yes" or "no." They could include a decision that, as of the date of the decision, there does not yet exist enough data to make a coverage decision. Permitting appeals of this type of decision would create accountability in those instances where the agency is simply dragging its feet and adequate data do already exist.

Allow Administrative Appeals of National Coverage Decisions

Under the current law, people who disagree with a national coverage decision are required to go directly to court, with no opportunity for administrative review. Given the tremendous medical and scientific complexity of national coverage decisions, we believe it would be productive to interpose a level of administrative review before proceeding to court.

While the creation of a Medicare court would reduce the problem, federal district court judges today usually do not have the training to comfortably consider the types of issues that need to be considered as a part of a national coverage decision. An administrative body with the proper expertise, in all likelihood, would make more informed judgments to the benefit of everyone involved, before any judicial review.

Confirm That Manufacturers have Standing as Aggrieved Parties in Coverage Decisions

The Administrative Procedure Act gives aggrieved parties standing to challenge broad rules imposed by an agency. To allow the challenges to broad policies at the local level that I referred to earlier, it is important for the Congress to clarify that manufacturers that sell products used by Medicare beneficiaries are aggrieved parties and have the ability to directly challenge policies that affect the access of beneficiaries to their products. This would reduce the appeals cost for the government because manufacturers would be able to address the broad issues in a single appeal, rather than require individual beneficiaries to bring perhaps thousand of individual appeals, with no guarantee that the process will actually resolve the real dispute.

Permit Courts To Order Corrective Action, Rather than Merely Remanding Back to the Agency

The current statute sets forth certain limitations on appeals from national coverage decisions, such as requiring that a court merely remand a dispute for further development of the record, rather than, in appropriate instances, fashioning a corrective order. That limit is out of step with what the Administrative Procedures Act authorizes in the review of any other administrative action. We see no reason to treat national coverage decisions differently from other agency actions and recommend deleting that limitation.

HCFA Unfounded in Claiming its Decisions Should not be Subject to Appeal Because it is a "Market Actor"

Medicare Holds Monopoly Position

We have heard HCFA say, in many different forums, that the agency is more akin to a private insurance company or market actor than a regulator. HCFA's reasoning seems to suggest that, because HCFA reimburses for items and services in addition to regulating, it ought to enjoy the same freedom from the need to publicly justify its purchases that *it perceives* private insurers enjoy. We do not agree with the comparison, or with the premise that private insurance companies do not have rigorous appeal processes.

Unlike a private insurance company, whose shareholders voluntarily choose to invest in that insurer, Americans have no choice but to pay the social security taxes that fund the Medicare trust fund. And thus when Americans become seniors who qualify to receive benefits under Medicare, at that point we still have no real choice but to participate in Medicare. Medicare quite simply has a monopoly position in the marketplace for health insurance for the more than 38 million beneficiaries who depend upon the program for health care coverage.

Market Forces Keep Private Insurers Accountable

In practical terms, this means that the fee-for-service side of Medicare does not have the same market place forces keeping it accountable that private insurers have. On a daily basis, private insurance companies must strive to make sure that their policyholders are happy with the level of services the insurance company provides. Otherwise, their policyholders will vote with their feet.

If a private insurer, for example, does not make appropriate coverage determinations, not only can individual beneficiaries complain to the insurance company, they and/or their employers can vote with their feet. They can switch to a different insurer. Indeed, because most private insurance is handled on a group basis, that gives the employers and other group representatives significant market power to ensure appropriate coverage decisions. That same sort of leverage does not exist in the individualized Medicare arena.

Not only do private insurers have to worry about their top line, they have to worry about their bottom line. If insurers make poor coverage determinations, such as failing to cover new technology that would save them money, their bottom line suffers, and the owners of the company and the capital markets hold the company accountable. With all that Congress must monitor, Congressional oversight of HCFA cannot create the same level of accountability, nor is it efficient to ask aggrieved parties to seek Congressional involvement whenever a dispute arises.

While there is choice within the Medicare system between fee-for-service and managed care plans, that choice does not create accountability in the coverage process for devices. The decisions that the HCFA Office of Clinical Standards and Quality makes set the standard in determining which devices beneficiaries can have access to, regardless of what part of Medicare is involved. Moreover, the significant differences between what the Medicare managed care plans and the fee-for-service part of Medicare offer in terms of access make it unlikely that competition between the two would ever hold HCFA accountable for the device coverage decisions HCFA makes.

For all of those reasons, the HCFA Office of Clinical Standards and Quality is not subjected to the same sort of marketplace pressures and accountability to which private insurers are subjected. The Congress must, therefore, look for an alternative means, such as appeals, to ensure that accountability.

The Medicare Fee-For-Service Appeals Process Should Be Updated

In 1997, when Congress created the Medicare+Choice program in the Balanced Budget Act, it took the opportunity to enhance the appeals process on the managed care side of Medicare. That Act—together with HCFA's implementing regulations—outlines an appeals process with explicit time limits for the various stages of review and incorporates review by outside parties. These key features should be carried over to the fee-for-service side of Medicare.

In fact, HCFA's reluctance to improve the Medicare appeals system seems out of step with the modern trend. Many private insurers (the same group to which HCFA likes to compare itself) appear to be enhancing their appeals processes in response to President Clinton's Consumer Bill of Rights and Responsibilities in Health Care. That Bill of Rights, which applies to Medicare, proclaims that "All consumers should have the right to a fair and efficient process for resolving differences with their health plans, including a rigorous system of internal review and an independent

system of external review." Yet HCFA seems to be resisting, for example, any effective system of independent external review for Medicare.

CONCLUSION

As you can tell from my remarks, many of these issues require statutory amendments to resolve. We support legislation to rationalize and improve the Medicare appeals process for coverage, coding, and payment decisions. We hope this Committee will give serious consideration to developing such legislation.

Thank you for this opportunity to present our views. We look forward to working constructively with you and the agency to develop appropriate solutions to these problems. I would happy to answer any questions you might have.

Chairman THOMAS. Thank you very much.
Mr. Kiesner.

STATEMENT OF FRANK J. KIESNER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ONCOTECH, INCORPORATED, IRVINE, CALIFORNIA

Mr. KIESNER. Thank you, Chairman Thomas. I am here to talk about fair access and timely access to benefits for cancer patients. Our company provides a service which takes the living tumor cells from cancer patients' biopsies into our lab, and we expose those tumor cells to the different chemotherapy drugs that an oncologist is considering using. We can identify a condition which is referred to as extreme drug resistance, and when that condition exists, the possibility that if that drug is given to the patient, that the patient will benefit from it is negligible. The service has been provided for over 50,000 cancer patients throughout the country from over 800 different hospitals, and if you look at the service from the viewpoint of the cancer patient, it eliminates the toxicity and lost time from ineffective therapy, and from that viewpoint and from the cancer patient's viewpoint, it is a humane service.

TransAmerica, acting as the carrier for southern California, has denied this service based on—and this is very important—based on a factual determination in 1995 that the service we provide is proscribed by a national coverage policy which was enacted in 1982. Administrative law judges have reached the conclusion that that 1982 enactment doesn't apply to what we do. Dr. Bagley of HCFA has written a letter to the San Francisco regional office that the enactment of 1982 does not apply to what we do. Hearing officers within TransAmerica, themselves, have reached the conclusion that that enactment does not apply to what we do, and, finally, the law department from TransAmerica has written a letter to our attorney acknowledging that the 1982 enactment doesn't apply to what we do. To this day, the carrier denies extreme drug resistance testing based on that 1982 enactment.

We have been through the hearing process within TransAmerica; we have been through an ALJ; we participated in negotiated rulemaking, and we appeared before the TAC Committee. Based on all of this experience, I would like to make some recommendations. First and most importantly, the local decision in relation to technology coverage for cancer patients must be done in an open, informed, and public forum where scrutiny can be imposed on the quality of the decision.

Second, the appellate process has got to be removed from the local carrier. Our experience is they side with the carrier, so much so, that even when the hearing officer will acknowledge that the 1982 enactment does not apply, in writing their opinion they will impose subsequent hurdles that we had not had notice of and cannot respond to.

Third, make the ALJ's technology decision binding on the carrier. In our case, there is one question that is, does the 1982 enactment apply to our technology? The ALJ made the determination after a 2-year process that it does not. TransAmerica says "We won't acquiesce in that ALJ decision, because it is limited to the few patients that were before the ALJ at the time." It took us 2 to 2½ years to get to the ALJ. They don't acquiesce, and we are in another cycle now where we have to go through the hearing officer, up to the ALJ, and that same issue is going to be decided, and I believe it is going to be decided the same way it was decided the first time. And what is the effect of this? Cancer patients don't get the benefits.

This Subcommittee has the power to do something very good for cancer patients, and that is provide an open environment for technology decisions to be made, and have an appellate process that has enough teeth in it so that when errors are determined to have been made, they can be reversed. In the absence of that, cancer research is going to be lost; innovation is going to be lost; companies like ours are going to perish before the skills and talents of our employees will ever reach the bedside. I don't believe this is in the best interest of the cancer patient. Thank you.

[The prepared statement follows:]

Statement of Frank J. Kiesner, President and Chief Executive Officer, Oncotech, Incorporated, Irvine, California

I am President and CEO of Oncotech, Inc., a pathology laboratory based in Irvine which provides cancer testing services to over 800 hospitals throughout the country. Oncotech has provided its Extreme Drug Resistance ("EDR") test for over 50,000 cancer patients, including thousands of Medicare patients. The purpose of the test is to identify, before chemotherapy is given, if the patient's tumor is intrinsically resistant to a chemotherapy drug under consideration. When a cancer patient is found to be extremely resistant to a drug, the probability that the patient will respond to that drug is negligible. This information is used to eliminate resistant drugs from therapy, thereby saving the cancer patient the toxicity, time and cost associated with a drug to which the patient is resistant.

Transamerica, the Medicare carrier for Southern California, continues to deny claims for EDR testing based upon a national non-coverage policy which has been found by ALJ's, by Transamerica Hearing Officers, by Transamerica's Law Department, and by HCFA, not to apply to Oncotech services.

Oncotech's experience, resulting from participation in the TAC, and Negotiated Rulemaking, both at the national level, and Transamerica at the local level, has led us to request your assistance to change, in a positive manner, the authority and process by which local Medicare carrier medical directors address new technology. In our view, the restrictive and troubling nature of coverage decisions which Congress previously identified within HCFA's Technology Assessment Committee (TAC), is present within Transamerica. This situation is in direct opposition to the best interests of cancer patients, good government and providers attempting to improve cancer care through new technology.

Respectfully, I believe that the following changes would be helpful to Medicare patients, the Medicare program and to Medicare suppliers and providers.

1. Make Coverage Decisions Open to Public Input and Scrutiny

Technology coverage decisions by local carrier medical directors should be open to public scrutiny. For example, Blue Shield of California has a technology review committee which publicly reviews its medical director's technology decisions. This com-

mittee is comprised of individuals who represent the interests of providers, hospitals, beneficiaries and the community. Blue Shield's medical director prepares a position paper on the coverage issue in question and is required to present that position in a public meeting attended by the committee members who are empowered to vote and providers, technology experts and members of the press who are allowed to comment. Dialogue and discussion which occurs in this format, precedes a public vote by committee members. This open, democratic process is the foundation for informed coverage decisions and for the acceptance of those decisions within the community. In this environment, at the March 2, 1994 meeting of the Medical Policy Committee, Blue Shield of California reached the following conclusion:

> "Drug resistance testing in oncology is accurate and reliable. This information can affect clinical decision making and lead to avoidance of ineffective and potentially harmful chemotherapeutic agents. Although there are few prospective clinical trials comparing standard therapy with chemotherapy chosen by in vitro assay, there are sufficient data to determine their safety, clinical utility and impact on clinical decision making."

In contrast, Transamerica, in relation to Extreme Drug Resistance has made local coverage decisions behind closed doors with no notice to suppliers such as Oncotech. Transamerica refuses to disclose its consultants by name or to provide for a public critique of its rationale. Oncotech has been blinded to Transamerica's coverage criteria, to its coverage related meetings and to the rationale for its decisions. The following excerpts of the October 1, 1998 Hearing Officer decision describes the coverage process followed by Transamerica:

> "The Carrier's Medical Director recently requested comments, in regards to the EDR assay from numerous oncologists. Their responses varied, however, the majority agreed that the EDR Assay and Drug Sensitivity Assay are based on the same principle. In addition, most of them have not used the technology. In one situation, three physicians commented that they had only sent two specimens for assay testing in the last seven years. Another oncologist determined that he could not recommend the use of EDR since his research did not show the effectiveness or usefulness of the EDR assay. Furthermore, I contacted the Carrier's Oncology Advisor and per our conversation with the Advisor agreed that both assays are based on the same theory and concert and I concur.
>
> The Carrier, acting within the scope of their authority, has determined that the EDR testing and Sensitivity testing are similar and achieve the same results. Therefore, at the present time, EDR assay falls within the guidelines of Section 50–41 of the Coverage Issues Manual and is excluded from coverage under the Medicare Program. Therefore, I am affirming the Carrier's position."

After reading the above description, however, Oncotech has no information concerning the identity of the physicians involved, their qualifications, the principle tying EDR to drug sensitivity or the extent and merit of one physician's research. Most importantly, Oncotech did not have an opportunity to respond to their concerns or add value.

Oncotech's scientific and medical expertise is renown within oncology. Oncotech's Board of Directors includes Dr. Vincent DeVita, past Director of the National Cancer Institute, Dr. Frank Meyskens, Director of the UCI Comprehensive Cancer Center, Dr. Trevor Powles, Director of the Breast Cancer Program at the Royal Marsden Hospital in London. Finally, our Scientific Advisory Board is chaired by Dr. Marc Lippman, Director of the Lombardi Cancer Center at Georgetown University. Yet, Transamerica will not provide a forum in which these and other leading physicians can participate openly and fairly.

2. The Review of a Technology Coverage Decision by Transamerica's Hearing Officers Should be Free of Carrier Bias and Written by Hearing Officers With Appropriate Technical Competence

A. In our experience, Transamerica Hearing Officers typically side with the carrier to the extent that when the published reasons for the claim's denial are overcome during the hearing, the Hearing Officer bases his decision upon new and previously undiscussed hurdles. The provider is left with an impossible burden. Our only redress is to appeal the decision to an ALJ, wait two years, and hope for objectivity.

B. Hearing Officers who are responsible to decide technology questions should have a background suitable for the issue at hand. If consultants are needed, their opinions should be given to the Hearing Officer at the time of the hearing when a

provider would have an opportunity to refute or comment if appropriate. It is our experience that consultants to the Hearing Officer are isolated from and unknown to the supplier. There is no opportunity for dialogue between the hearing officer, provider and consultant.

3. Require Local Medical Directors to Integrate ALJ Technology Coverage Decisions into Technology Coverage Policy

The two to three year appellate process within Transamerica, culminating at an Administrative Law Judge preceding, was our only mechanism to redress Transamerica's non-coverage decision. We were prohibited from going into the legal system until our remedies within Transamerica and the ALJ were exhausted. When, as occurred in this case, Transamerica employed a tactic of non-acquiescence to the ALJ's decision, the three year appellate process offered no real redress. Today, Transamerica's approach has left Oncotech in the identical position in relation to future claims that we were in when we began the appellate process three years ago. Favorable ALJ decisions are meaningless to suppliers if Transamerica's Medical Director refuses to integrate them into subsequent policy. This non-acquiescence tactic was overturned in Duggan v. Bowen, 1998. The judge commented,

> "It is remarkably unfair for the fiscal intermediaries that make initial coverage determinations neither to take into account nor to 'acquiesce' in decisions made by either an ALJ or the Appeals Council. Because the agency is committed to this policy of internal non-acquiescence, which guts the precedential value of any individual's successful appeal, many plaintiffs are hit with another denial almost immediately after they have succeeded in overturning an earlier coverage denial. Plaintiffs are on a merry-go-round. They have a right to get off."

4. Provide a Mechanism for Independent and Immediate Review of Erroneous Carrier Newsletter Pronouncements

Transamerica used minutes from HCFA's disbanded TAC Committee as the basis for their June 1998 newsletter which communicated to the practicing medical community that EDR and the human tumor stem cell chemosensitivity assay are one and the same. This newsletter undermines the very core of the EDR technology and has affected Oncotech's credibility among its clients. Transamerica's newsletter is in direct opposition to ALJ decisions, a letter from Transamerica's Law Department to Oncotech, a memo from Dr. Grant Bagley of HCFA to the San Francisco regional office and recent Hearing Officer decisions. To date, Transamerica has refused to clarify or modify this statement.

5. Provide a Safe Harbor for Discussion of Coding and Fraud/Abuse Questions Relating to New Technology

Providers of new technology need assistance from their local carrier in questions relating to coding and fraud and abuse. New technologies may not fit into established mindsets. It is essential that a procedure be put into place for providers and their local medical director to openly discuss questions and concerns within a safe harbor. As a result of my participation in the Negotiated Rulemaking process for clinical diagnostic testing, I have been exposed to the incredible sophistication of Medicare's coding system and its ambiguities. Even large national laboratories with extensive legal and reimbursement departments have difficulty. Local medical directors must have a vehicle to deal with companies providing emerging technologies, as the companies attempt in good faith to fulfill the regulatory requirements associated with coding and fraud and abuse questions.

6. Define and Make Public the Criteria for Technology Coverage

The criteria against which new technologies are measured should be specific and public. Criteria such as "investigational" or "experimental" are too general. They represent a nebulous standard which does not guide the development of new technologies. Companies attempting to introduce new technologies are unable to identify benchmarks which, when reached, will assure coverage.

7. Accelerate the Appellate Process in Oncology

Congress has provided accelerated processes for the FDA's approval of cancer related pharmaceuticals. Such a process for cancer related testing is warranted. Companies such as Oncotech cannot wait three years to have a coverage issue reach an open hearing at the ALJ level. Our country invests hundreds of millions of dollars each year in cancer related research. A local carrier medical director, operating within a closed door environment and dealing with technologies in which they are

untrained, creates institutional impediments to the translation of research into available clinical tools. Oncology specialists under contract who are able to visit providers and work with them on a fully informed basis would be of great assistance to medical directors who are reluctant to leave their administrative bastions.

Finally, I feel it necessary to distinguish the procedures followed at the national level from those discussed above. Specifically, we have observed that the coverage questions handled by the HCFA staff in Baltimore have been done in a most professional and competent manner. They have been accessible, objective and helpful. The principles of open and informed decision making are being followed within the Negotiated Rulemaking process. We must find a way to have these principles imposed upon local coverage issues.

Thank you for your interest in this matter.

Chairman THOMAS. Thank you very much, Mr. Kiesner.
Dr. Plested.

STATEMENT OF WILLIAM G. PLESTED III, M.D., MEMBER, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION

Dr. PLESTED. Thank you, Mr. Chairman. My name is Bill Plested. I am a thoracic and cardiovascular surgeon from Santa Monica, California and a member of the Board of Trustees of the American Medical Association. Reform of the Medicare coverage decision and appeal process is long overdue. We commend the Chairman for his efforts over the last 2 years to shed light on the procedures employed by HCFA to generate national coverage decisions. We also commend the Chairman and the Ranking Member for enlightening HCFA regarding the difference between coverage policy decisions and program integrity concerns. In fact, we agree that HCFA's reluctance to separate its policies on coverage from its policies on fraud and abuse is a major source of the coverage policy problem facing Medicare patients and their physicians. Provision of high quality medical care to patient, not HCFA's efforts to find fraud and abuse, must serve as the foundation of efforts to reform the Medicare coverage policy process.

Coverage decisions should be based on evidence of clinical effectiveness obtained from peer-reviewed medical literature and consultation with practicing physicians. We have five major concerns with the current Medicare coverage and appeals process and the direction of HCFA's reform efforts to date. First, local coverage policies should be developed through a standard, open, scientific process. Once developed, the new standards of openness, timeliness, and evidence-based decisionmaking must be applied to all levels of the coverage policy process whether local, regional, model or national. Although the physician community has made these points to HCFA multiple times, HCFA's Office of Clinical Standards and Quality has told us that it has no control over the local carriers. Incredibly, the carriers that develop coverage policies at the local level are accountable to HCFA's Office of Program Integrity. It is clear to us that if the new national standards are not applied to local carriers, then carrier coverage decisions will continue without any real standards or oversight. The AMA is not suggesting that all coverage policies be established at the national level, but there are numerous examples of flawed carrier policies, and a standardized process is needed. For example, some carriers deny Medicare coverage for preoperative evaluations needed to clear patients for

surgery. These are not screening tests; they are vital to patient safety and must be covered. Another example is Florida's carrier's policy that lipid profiles are not covered for diabetic patients. This directly conflicts with published guidelines from the American Diabetes Association.

Second, program integrity must be treated as a separate issue from coverage. In HCFA's outline for a new Medicare coverage process, program integrity was cited as one of the reasons for reconsideration of Medicare coverage. We strongly disagree. If a service is believed to be subject to fraud or abuse, then HCFA should find a means to target the specific fraudulent or abusive practice. Mr. Chairman, we understand that you and Mr. Stark have already written to HCFA to state concerns that HCFA has divided responsibility over Medicare coverage decisions between the Office of Clinical Standards and Quality and the Medicare Integrity Program; we wholeheartedly agree. Innovations in medical practice and technology can only be made available to patients if Medicare coverage policies are based on clinical effectiveness, not program integrity.

Third, entry into the standardized coverage process must be simple. We do not support a bureaucratic FDA-type application process.

Fourth, a fair and independent appeals process needs to be developed. The appeals process takes far too long; involves over complex regulations; costs too much, and lacks a truly independent adjudicator. Essentially, the current appeals process lacks any semblance of fairness or due process. A timely and independent appeals process must be established using an adjudicator who has expert knowledge of the Medicare Program.

Finally, a means should be established for appealing policies, not just individual claims. No vehicle exists for addressing problems with local, regional or model coverage policies. Patients can only appeal individual denials.

In closing, the current Medicare coverage and appeals process is not patient-centered. In fact, there is no process. We have only a confusing morass of Medicare regulations that do considerably more harm than good to physicians' good faith efforts to provide high quality care to their Medicare patients. Thank you, Mr. Chairman.

[The prepared statement follows:]

Statement of William G. Plested III, M.D., Member, Board of Trustees, American Medical Association

INTRODUCTION

Mr. Chairman, Mr. Ranking Member, and Members of the Committee, my name is Bill Plested, MD. I practice cardiovascular and thoracic surgery in Santa Monica, California, and am a member of the Board of Trustees of the American Medical Association (AMA). The AMA appreciates the opportunity to testify on these important Medicare issues—coverage decisions and beneficiary appeals.

Reform of the Medicare coverage decision process is long overdue, and the AMA commends the Chairman's efforts over the last two years to shed light on the procedures employed by the Health Care Financing Administration (HCFA) to generate national coverage decisions. The AMA also commends the efforts of the Chairman and Ranking Member to enlighten HCFA regarding the difference between coverage policy decisions and "program integrity" concerns.

In fact, the AMA believes that HCFA's reluctance to separate its coverage and quality of care policies from its policies addressing fraud and abuse is the root of the coverage policy problem facing Medicare beneficiaries and their physicians.

There is a saying that, "when your only tool is a hammer, every problem looks like a nail." In its management of the Medicare program, HCFA seems to approach virtually every issue, whether it involves national or local coverage policy, payment, coding, or quality, as an issue of waste, fraud and abuse. This singular focus on fraud has become even more pervasive among the Medicare Part B carriers than it is within the HCFA central office. In addition to operating in an environment that places a premium on recovery of so-called "overpayments," the carriers have also intensified their pursuit of fraudulent and abusive practices to an excessive degree to protect their current functions and budgets from being shifted to the new Program Safeguard Contractors, who are perceived competitors. Accordingly, even when HCFA establishes sound national coverage policies, these policies are sometimes subverted by local or regional carriers that place unwarranted constraints on covered benefits.

The AMA believes that our patients who are insured by Medicare should have access to the same clinically effective innovations in medical practice and technology that we are able to offer our privately insured patients. These innovations will only be available to beneficiaries, however, if Medicare coverage policies—whether national or local—are based on the relative clinical effectiveness of the innovations, not on "program integrity" concerns.

AMA Recommendations for Reforming the Coverage and Appeals Process

Provision of high quality medical care to patients must serve as the foundation of efforts to reform the Medicare coverage policy process. Coverage decisions should be based on evidence of clinical effectiveness obtained from medical literature and consultation with practicing physicians, especially the national medical specialty societies. Once developed, the new standards, including standards of openness, timeliness, and evidence-based decision making, must then be applied to all levels of the coverage policy process, whether local, regional, model, or national.

After enactment of the Balanced Budget Act of 1997, representatives from the AMA and selected national medical specialty societies met several times with HCFA staff to discuss development of the national coverage policies that would govern implementation of Medicare's expanded preventive benefits. We viewed the consultative process of HCFA obtaining the most current clinical and scientific information on effective preventive approaches from medical specialty societies as a positive development, and an example of a good approach to coverage policy making. In correspondence with the HCFA Administrator and comments on HCFA's September 25, 1998 Town Hall meeting, we have recommended that HCFA follow a similar approach.

HCFA's Coverage and Analysis Group has been generally receptive to our recommendations. We were pleased that the Charter for the new Medicare Coverage Advisory Committee (MCAC) indicated that MCAC functions will involve reviewing and evaluating medical literature, technical assessments, and information on the effectiveness and appropriateness of medical services. We were also pleased that HCFA's solicitation of MCAC nominations seemed to emphasize the importance of individuals with expertise in medical practice. In addition, HCFA's use of proposed rules with opportunities provided for public comment has allowed for significant medical input into the regulations governing the new preventive benefits. Nonetheless, we continue to have five major concerns about Medicare coverage decision and beneficiary appeals processes.

1. Local coverage policies should follow standards

When the new procedural standards for national coverage decisions are developed, they should apply to all levels of Medicare coverage decision making. Although the physician community has made this point to HCFA consistently over the last two years, the Office of Clinical Standards and Quality continues to state that it has no control over the actions of local and regional carriers because the carriers are accountable to the Office of Program Integrity. This means that the new national standards will not be applied at the local level. We are also not aware of any HCFA plans for oversight of carrier development of local policies.

The combination of a lack of enforced standards for carriers and the single-minded focus on fraud and abuse are a serious concern, especially because the carrier policies frequently evolve into de facto national coverage decisions. This is actually the purpose of "model" policies, which are policies developed by a few Medicare carrier medical directors (through a process viewed uniformly as a "black box") that are dis-

seminated to other carriers for their use. With guidance from HCFA's Office of Program Integrity, the durable medical equipment carriers are also making policies that effectively serve as national coverage decisions, even though they were established as regional carriers.

The AMA is not suggesting that all coverage policies be established at the national level. While some local carriers obtain input on proposed policies from practicing physicians through consultation with their carrier advisory committees, local policies often are simply based on a statistical analysis of claims that indicates a higher frequency of a particular procedure code than the national average. As the following list illustrates, numerous examples are available of local policies that directly conflict with the views of practicing physicians about good standards of medical care:

• The April 19 Washington Post (p. 2) indicates that, despite Medicare coverage of preventive services, many beneficiaries are not getting needed preventive care. One example cited is the low percentage of elderly patients with diabetes receiving blood lipid tests. What the article fails to note, however, is that at least one Medicare carrier, which handles the state of Florida, published a local coverage policy for blood lipid tests in its July/August 1997 bulletin indicating that diabetes is not among the covered diagnoses for these tests. This policy is in direct conflict with published guidelines from the American Diabetes Association and, in 1999, physician claims for lipid tests are still being routinely denied for diabetic patients in Florida. The carrier cites as its rationale that the procedure codes for lipid tests "have been billed substantially more in Florida than at the national level for multiple specialties. Further analysis of the data indicates that these procedure codes ... are being billed with diagnoses that do not support medical necessity."

• The primary focus of the Post article is preventive care exams. HCFA did not accept repeated advisories from the AMA, however, that it was not sufficient for regulations on the new preventive benefits to address only specific screening tests, but that they needed to clarify Medicare coverage for visits where physicians counsel patients about risks and benefits of preventive care. Given HCFA's lack of national guidance on coverage for preventive visits and its overzealous pursuit of fraud, it is not surprising that many carrier policies are developed specifically to reduce the number of covered Medicare claims for physician visits. For example, the New York carrier, citing an Office of the Inspector General report that "Medicare should not be paying for 30% of all physician services claims," is routinely denying claims for physician visits to skilled nursing home patients. Even after obtaining documentation showing that the visits were needed to control heart failure (potentially avoiding hospital admissions) or treat skin rashes, claims for visits are denied as not medically necessary and no more than one nursing home visit per month is covered.

• It is standard clinical practice in urology to give a man who complains of lower urinary tract symptoms a prostate-specific antigen test (PSA). In many localities, patients have no idea if the test will be covered because Medicare's coverage policy depends on the test result. Moreover, nearly half the carriers will not pay for the test if the diagnosis turns out to be enlarged prostate.

• Previously, Medicare covered removal of pre-malignant skin lesions (actinic keratoses) by any method, but in 1996 the Florida carrier instituted a local policy restricting coverage only to certain lesions. Lesion removal was considered medically necessary only if the lesions were symptomatic, on certain parts of face, or if the patient had a particular medical history or condition. The carrier ignored information provided by dermatology specialty societies and implemented a policy totally contrary to the standard of care. The problem was then compounded when a carrier workgroup was formed and the restrictive lesion removal policy became a "model" policy for use throughout the country.

• In some localities, claims for the physical evaluation necessary to clear patients for anesthesia and surgery are being denied as noncovered because "Medicare does not cover screening services."

• Monitored Anesthesia Care (MAC) is a form of anesthesia care that involves close monitoring of sedated patients who may need to either be placed under general anesthesia or revived, and it is intended to be covered just like general or regional anesthesia. A large number of carriers adopted a policy limiting MAC coverage to certain diagnoses. Coverage was denied for a number of important services for which anesthesia is clearly a requirement, such as breast biopsies and pacemaker insertions. Although some carriers have subsequently abandoned the policy due to concerted informational campaigns by anesthesiologists, uneven coverage across localities is likely to persist.

• As part of the randomized clinical trial of Lung Volume Reduction Surgery, HCFA decided that all patients, including those chosen for surgery and those receiving only non-surgical care, must receive pulmonary rehabilitation services. For those

Medicare beneficiaries who are not in the clinical trial; however, coverage of pulmonary rehabilitation varies widely across localities. If HCFA believes that pulmonary rehabilitation is effective, then it should be a covered service for the other patients that would benefit from it.

• In many localities, carriers establish arbitrary limits on psychotherapy services, even though the Congress has not limited the number of Medicare-covered psychotherapy services for psychiatric patients.

2. Program Integrity should be treated as a separate issue from Coverage

In HCFA's outline for a new Medicare coverage process, which was provided prior to September's Town Hall meeting for public review and comment, "program integrity" was cited as one of the reasons for reviewing Medicare coverage policies. A comment letter submitted by the AMA and more than 30 national medical specialty societies stated that program integrity concerns should not be a reason to discontinue or reconsider Medicare coverage for a beneficial patient service. If a service is believed to be subject to fraud or abuse, then HCFA should find a means to target the specific fraudulent or abusive practice.

We also stated objections to the HCFA suggestion that coverage policies be reviewed or reconsidered for services that represent a significant expense to the Medicare program, even if the medical effectiveness of the services was not demonstrated prior to Medicare coverage. In fact, if a service is being frequently provided, the most likely explanation for its high utilization rate is that physicians consider the service to be very beneficial for their patients. Too often, as noted in some of the above examples, local carriers decide to limit Medicare coverage for services solely because the frequency of service provision differs from average, "normal," or "expected" utilization. While HCFA may continue monitoring information about clinical effectiveness as it becomes available and, based on new evidence or research, decide to revisit previous coverage decisions, frequency of use alone is not an appropriate reason to limit or withdraw coverage.

3. There should be no application process

HCFA should engage in an ongoing effort to stay abreast of new developments in medical practice and technology, working to ensure that Medicare's coverage policies provide patients with access to all reasonable and necessary diagnostic, therapeutic, and preventive medical services. Instead, HCFA seems inclined to have the first step in its coverage policy process be the submission of an "application" for coverage, similar to the Food and Drug Administration procedure. The AMA believes that such a process would likely preclude small groups of beneficiaries and physicians, or any entity with limited resources and experience in the coverage process, from bringing forward promising innovations for Medicare review. Even if those with fewer resources manage to complete the application process, HCFA is more likely to devote necessary resources to reviewing applications from large corporate entities than, for example, a new diagnostic or surgical procedure developed by a small medical group.

4. A fair and independent appeals process should be developed

The process of appealing denied or downcoded claims takes far too long, is not geared to address the voluminous and complex regulations governing the Medicare program, can be far more expensive to pursue than the amount that is actually in dispute, and, even if a beneficiary or physician pursues an appeal to the highest level, there is no ability to get an independent judgment. Timelines should be established and enforced. Judges and others involved in the appeals process should be required to have expertise in Medicare, not Social Security, which is the topic with which the current administrative law judges hearing Medicare appeals are most familiar. So-called "fair hearings" are not really fair because the hearing officers are employed by the same carriers that deny the initial claims. Many physicians fear even requesting a fair hearing, out of concern that carriers may view physicians who appeal as "troublemakers" and, therefore, that carriers may begin scrutinizing their claims even more closely. Also, the final level in the decision process should not be the Department of Health and Human Services. As with other legal questions that are resolved in U.S. courts, there should be a means for obtaining a judgment on appeal that is independent of the agency involved in the initial claim denial.

Often physicians also have no meaningful opportunity to appeal claims that have been downcoded or denied based on a carrier audit. When claims are subjected to postpayment audits, for example, physicians are given three options for responding to the carrier. In order to accept two of the three options, physicians must waive their appeal rights. The third option preserves the right to appeal, but physicians choosing this option must subject their practices to a carrier audit of a Statistically

Valid Random Sample (SVRS) of claims. An SVRS can cause monumental upheaval and disruption for a practice, even bringing office operations to a complete halt, as well as leading to expensive legal bills.

Essentially, the current appeals process lacks any semblance of fairness and due process.

5. A means should be established for appealing policies, not just individual claims

The coverage policy notices that HCFA has published over the past 18 months provide good avenues for requesting reconsideration of proposed national coverage policies, although the AMA does not believe that it is necessary for HCFA to go through notice and comment rulemaking for every national coverage decision. We anticipate that HCFA will continue to provide vehicles for commenting on and seeking revisions in national coverage policy decisions, and this process should become even more effective with the formation of the MCAC.

No similar vehicles exist, however, for addressing problems with local, regional, or model coverage policies. Under the current system, if a carrier establishes a bad coverage policy, beneficiaries have no vehicle for appealing the policy decision, they can only appeal individual denials. Moreover, the outcome of any given appeal sets no precedent for other appeals, so the potential exists for a perpetual cycle of the same issue being questioned on the same basis over and over again. In fact, HCFA does not even consider the policies developed by local and regional carriers as Medicare coverage decisions, but instead HCFA views them as program integrity policies. This conflict between coverage and "program integrity" must be resolved if patients and physicians are to have confidence in the overall integrity of the Medicare program.

Beneficiaries and their physicians should be able to offer input into and appeal all coverage policy decisions, not just national decisions.

CONCLUSION

The current Medicare coverage and appeals process is not patient-centered, but instead is part of the confusing morass of Medicare regulations that do considerably more harm than good to physicians' efforts to provide high quality medical care to their elderly and disabled patients. The AMA applauds the Committee's interest in reforming this process. On behalf of the AMA, I offer you our services in working further with the Committee and the Congress to effectively address these important matters. Thank you again for the opportunity to testify today.

Chairman THOMAS. Thank you very much, Dr. Plested.

This is a little off the mark, but since it was volunteered by my colleague from California, if you have a reaction, I would like some response to it or if you are familiar with it or especially if any of your organizations have a position on the idea, that a number of folks wonder why we have to go through FDA and then to a certain extent duplicate the process in going through HCFA, although there was an attempt to explain that they really are different. Some of the explanation, to me, wound up as a distinction without a difference or a very easily contracted extension of FDA reviewing it and not two separate processes in both the question of whether or not if is safe, and, two, is it efficacious? Do you think that the idea that it might be combined in one step makes sense? I mean, anytime I can eliminate the bureaucratic steps—if you haven't thought about it, if it is new to you or you are focusing primarily on HCFA and its appeals process rather than the larger question, it just seems to be especially in the areas of medical devices in which we are moving relatively rapidly in change, that this might be something that would be useful. Anyone wish to comment?

Mr. ROSEBROUGH. Just one quick comment. I don't think HIMA has a stated policy at this point, so for HIMA I don't think there is any, but the concern that I am sure that both they and I would

express is the local coverage policy issue is one that we endorse. We think the diffusion of technology is enhanced by having the ability for local coverage decisions, and if you move that to the FDA, I am sure we would—I am not sure it makes much difference which of the two agencies attack that as long as they are funded appropriately and can get at that issue, but if you move it to the FDA, we would want to make sure that there was some local coverage capability in addition to the national coverage decisions.

Mr. KIESNER. I have a little different perspective. I think if you look at it from the point of view of timeliness, there are a number of new therapies that are now being developed that are targeted toward specific genetic and other molecular conditions within the cancer patient. If you take the time to have the FDA approve those therapies and then add another 2 or 3 years on top of that, it makes no sense, and the scientific data, the clinical studies, and so forth, that are used to validate the approval by the FDA are directly related to what medical conditions Medicare should pay for.

Chairman THOMAS. I believe I am correct on that point that if FDA approves pharmaceuticals, they will be reimbursed by HCFA, but I am just thinking that more and more it is a combination of the drugs, as you say, therapies, which are a combination of a number of items not just the drugs themselves, so that that would be a potential—timeliness was a theme through all of your arguments within the structure.

The gentlewoman from Connecticut indicated that the Department of Labor said 15 days was appropriate. We are sitting here trying to get the government to respond in 60 days or 30 days, but it just seems to me that somewhere between 400 days and 30 days, there is a number that is appropriate both for a timely review process and for an expeditious decision, and I won't pin you down for the number of days, but my guess is in the decisions that you folks have to make, they are more often on the 30-, 60-, 90-day timeframe and not the 400-day timeframe. Is that a reasonable assumption?

Mr. ROSEBROUGH. That is a very reasonable assumption.

Chairman THOMAS. I thank the gentleman. Does the gentlewoman from Florida have any questions?

Mrs. THURMAN. Mr. Chairman, or maybe one of the panelists can explain this to me. Generally, I found in government that a lot of the times we implement things because we think there is a problem out there, and then we stretch it a little and then these kinds of things result from this. I wasn't here in 1982, and it sounds like some of you have had some experience with this, and maybe Mr. Chairman or somebody—what do you think created these steps in the first place? How did we get here today? Somehow, I am missing something, I mean, especially with the fraud and abuse going there. I mean, I don't know, and if somebody could help me with that, I would be very appreciative.

Dr. PLESTED. I will be happy to take a stab at that.

Mrs. THURMAN. And I would appreciate it, and if you can't, we will try to find somebody that can, but it just seems alarming to me that I am missing something, because we don't go out looking for trouble, generally.

Dr. PLESTED. I am sure the Chairman can tell you, there are basic, fundamental flaws in the Medicare Program, and the tendency is to kind of not bite the hard bullet and look at the basic, fundamental flaws and to look at something simple like the Fraud and Abuse Program that bludgeons physicians and hospitals, and this is added to by the fact that during this period of time we have had two phenomenal explosions. One is the size of our Medicare population, and the other is the technology that you hear about, and if you put these all together, we are looking at the fact that we have got to get the basic, fundamental reform. In the meantime, we have to protect today's beneficiary, and that is what we are all talking about; how do we best do that today while we, hopefully, get back to the question of fundamental reform?

Mrs. THURMAN. Do you think there is something in here that could create a problem that seems to be the reason there is so much resistance to change? I mean, maybe I should have asked HCFA that, but I am just—maybe you all can help me with it—but I am just curious as to why they seem so adamant or trying to change but still have some concerns?

Mr. ROSEBROUGH. I think none of us by nature look for external review of our work, and, you know, whether you are in the private sector of public sector, getting an external review is always a painful experience.

Mrs. THURMAN. Yes, it was.

Mr. ROSEBROUGH. It is my experience that getting—in our position, the marketplace gives us our second opinion pretty quickly, and we have to react to it. That is a painful experience, but it is fruitful for all the parties involved. I believe not having an appeals process with some external pressure to it creates a situation where that if I were probably a member of HCFA, I would not be looking for external help either, but I think it is often an appropriate situation.

Mr. KIESNER. You know, I think that the answer to what you ask may be related to really, what do you believe? And if you believe that the Medicare Program is on a road to financial debacle; if you believe that the way to save the program is through denying your claims; if you believe that the providers are basically out to exploit the system, you are going to have one logic, one structure. On the other hand, if you believe that Medicare has a duty to the patients; if you believe that the role of the carrier is to determine ineffective from effective therapy, and if you believe that basically physicians and other providers are people of integrity and they just want to exercise their best judgment, then you are going to have a totally separate system.

Mrs. THURMAN. From a standpoint of the carriers—and one of you talked about how the system—you know, we ought to get the carrier to have to stay with whatever the decision is, but, at the same time, one of you said that generally when you go through this—I guess it was on the——

Mr. ROSEBROUGH. The administrative law judge?

Mrs. THURMAN. That they actually were kind of going with a carrier when they made the decision. Is there a bottom line money issue? I mean, probably what you asked me or said about what your philosophy is, but on the other side of it, I mean, is there—

particularly as our health care changes and how we get our moneys into the pockets and those kinds of things—is there a part of that going on because of the cost of new initiatives that you think maybe some of this is being stopped at least from those local folks?

Mr. ROSEBROUGH. Well, of course, there is both money and clinical practice decisions being made at all the places in the system, and people are trying to, I believe, in general, do the best job they can in doing that. What we need to have is some certainty that we lay out a set of rules; we work by the set of rules; we live by the set of rules; get good comments on that set of rules, so when making those decisions in an open forum—because everyone is trying—in my opinion, 90 percent of the people doing this work are trying to do the best thing for what they see as good for the Nation and patient, and the issue is getting a nice, clean set of rules that works rapidly; gets good public comments, so we can make those decisions in an appropriate forum.

Mrs. THURMAN. OK, thank you.

Chairman THOMAS. The gentlewoman from Connecticut wish to inquire?

Mrs. JOHNSON of Connecticut. HCFA has acknowledged that national coverage determinations are not generally appealable so that if you aren't satisfied with a national coverage decision, you can appeal it to the Medicare Coverage Advisory Commission. Is that satisfactory? I don't want a long answer; I want a short answer, just in your view, because I have other questions.

Mr. ROSEBROUGH. We don't believe so, no.

Mrs. JOHNSON of Connecticut. OK. Anyone think it is? Now, I don't think it is either, clearly.

When you look at FDA and HCFA, are there any recommendations you would make to bridge that gap?

Dr. PLESTED. Mrs. Johnson, currently, that changes FDA's mission, and the thing that we would keep coming back to is that we must have a standardized process. The process being scientific and open, and so forth, is what is really important. The players in the process could change, and there certainly could be a place for FDA in this, but what we need from them doesn't fit their current mission, and——

Mrs. JOHNSON of Connecticut. Having dealt with both FDA and HCFA, are there any reasons why we should automatically cover whatever FDA has certified?

Dr. PLESTED. Absolutely not.

Mrs. JOHNSON of Connecticut. What about the national guidelines? More and more of the big companies, the managed care companies, are using specialty-developed guidelines for asthma management, cardiac management, diabetes, and these are pretty well out there. Should we be looking at when the majority of private sector companies have adopted certain guidelines that Medicare would automatically adopt those? Would that help?

Dr. PLESTED. Possibly, but, again, you would need to have a process, and that process could certainly include other entities who have gone through a similar process and reached the conclusion. As long as your process says that you need to have a thorough review of the science and open input and everything else, someone who

brings you a work product developed by a similar process could certainly be accepted, yes.

Mrs. JOHNSON of Connecticut. And that is the thing, just like they did in JCAHO and things like that. Should we repeating the process if it has been gone through and it has been solid enough so that a majority of actors in the health care service sector are providing it? I mean, how do we define that group of decisions that the government should not be remaking?

Mr. KIESNER. I think our experience is that that is very difficult, because there is wide diversity within the commercial sector between guidelines that their institutions would adopt, whether it is a cancer center or whether it is a payer, and there still has to be some way to integrate all those into a final decision that is meaningful.

Mrs. JOHNSON of Connecticut. Should there be a shorter timeframe for decisions in which there has been a lot of national activity?

Mr. KIESNER. I think there should be, and I think the real question is how do you select those subjects that are raised to the national level? And I think that the people in Baltimore are working hard to get the process defined and in place in order to deal with those things more quickly.

Mrs. JOHNSON of Connecticut. In your experience, is there a way we could keep an overview of the local decisions that are made and when there is a critical mass of decisions in a certain area, pop that up to the national level, so there would be greater uniformity?

Mr. KIESNER. I think that that is a little difficult today, because there is so many cows that are out of the barn, so to speak. On the other hand, if we are looking at new technology that is as complex and sophisticated as found in the field of oncology, it makes a great deal of sense to have it go to a national policy decisionmaking body, and do it much earlier before you get the diversity.

Mrs. JOHNSON of Connecticut. Well, particularly in these illnesses in which we are really doing a lot of research and the techniques of diagnosis and treatment are changing rapidly, do we really want to put ourselves in the position of the Federal Government going through a panel and science all over again or if the oncologists have decided that this has promise and it is available to the working people of America under 65, is there a point at which, particularly in these cutting edge things, that we ought not to say—I mean, that has been the problem with clinical trials. If that is your only option and you are going to die, why should you at 65 or 68 or 75 or 85 not have the same option of getting to that care as somebody covered in one of our employer programs, many of which provide coverage of clinical trials? So, I think we need to think of how we can radically simplify this process.

One of the things that has destroyed Medicare in my estimation—and I think it is a system in systemic collapse—is the explosion of medical actions that can be taken. They cannot price them; they cannot follow them; we can't do this. So, we have to find a way to make this whole process of coverage decisions far more state-of-the-art and timely, and I appreciate your good testimony today; it was really impressive.

Dr. PLESTED. Mrs. Johnson, could I comment on one further thing about that, because I certainly do agree with you, and it comes back, again, to the point of having a standardized, uniformed process by which the decision is made. We certainly can't overwhelm HCFA with making all the decisions, but we have to know that the local carriers follow a process that is reasonable, so that then that can go on up.

Mr. ROSEBROUGH. And that process is committed to and followed as opposed to just being published.

Mr. KIESNER. And that there is an appeal oversight aspect to the procedures that have teeth.

Chairman THOMAS. And I still can't—and, as I said, we got this today, finally, and I am pleased we announced the hearing so we could get it. I believe it was a coincidence that it was released today; keep forgetting that. [Laughter.]

I just do not understand—and we are going to continue to push—there is no reason it isn't transparent. There is no reason why we can't use, heavily, third-party input early in the process so that they can't say they didn't know. We have got to break this argument that all expertise resides in-house, and that, ultimately, they are the ones who control.

Because what bothers me the most about this process, when you begin to look at it, is that this whole business of local review looks a whole lot more like the IRS procedure used to than I want it to; that it looks a lot like cost control, and it isn't really in the interest of the beneficiary, but too many people knee-jerk in terms of the government structure thinking that our review process is better than theirs, that is, government versus the private sector, and I am absolutely convinced it is not; it is the beneficiary who is suffering. They are suffering because there is inconsistency of the best medical practice applied. There are people who are trying to provide services who are being shorted funds, because it is not just weeks or months before you wind up getting a decision to be paid; it is months and years, and that is just simply wrong.

So, I appreciate your willingness to come forward. I do wish you will take a look at this process. There is no question it is better than the old one. The question is, is it good enough the way it has been presented? And if we are going to have a chance to review it and make some changes, let us do it as good as we can, so I would appreciate it if you would get back to us, especially if you are going to respond to the notice. I would like to have a copy of what you have sent, and, if you are not, as I told the other panel, I would love to have your ideas as well, because if it is good, we are going to move it; if it isn't, we are going to try to change it. And I appreciate very much your testimony.

[The following was subsequently received:]

HEALTH INDUSTRY MANUFACTURERS ASSOCIATION
WASHINGTON, DC 20005
July 19, 1999

Jeffrey Kang, MD
Director
Office of Clinical Standards and Quality
Health Care Financing Administration
Baltimore, MD 21244

RE: Federal Register Notice; Procedures for Making National Coverage Decisions-HCFA–3432–GN

Dear Dr. Kang:

On behalf of our more than 800 members, I would like to thank you for your efforts in preparing the recent Notice, which sheds light on the process the Health Care Financing Administration (HCFA) will use to make national coverage decisions for the Medicare program (64 Federal Register, No. 80, pages 22619–22625, April 27, 1999).

The Health Industry Manufacturers Association (HIMA) is a Washington, D.C.-based trade association and the largest medical technology association in the world. HIMA represents more than 800 manufacturers of medical devices, diagnostic products, and medical information systems. HIMA's members account for nearly 90 percent of the $62 billion of health care technology products purchased annually in the United States, and more than 50 percent of the $147 billion purchased annually around the world. We at HIMA know that you share our view of the importance of the Medicare coverage process. Medicare coverage means patient access to state-of-the-art medical care for our most vulnerable citizens. If the coverage process is not clear, if it results in unnecessary delays, if it is not sensitive to the medical innovation process, beneficiaries will pay the price—appropriate care will be denied or unduly delayed, and medical progress will be inhibited. We are pleased to see that this Notice contains a number of specific steps to make the national decision making process more open and understandable to the public, that it explains the way the new Medicare Coverage Advisory Committee will assist in this process, and that it makes an attempt to give the public a sense of how long the various elements of this process will take.

We at HIMA appreciate the frank and open dialogue we have had with you for the past year concerning the need to modernize the Medicare coverage decision making process. HCFA has clearly made progress in initiating reforms in this area, and we submit these comments in the hopes that you will further refine and formalize these first coverage process reforms, and that you will consider putting in place certain steps not contained in the April 27 Notice.

Our comments reflect two key concerns. First, we are concerned that the national decision making process is too long. Indeed, the review process set forward for at least many technologies in the Notice exceeds their product life cycles. We have a number of suggestions on how to speed the time it takes to review new technology and make it available to Medicare beneficiaries. Second, we have suggestions on additional elements to include in the national coverage process that we believe will strengthen it. In addition, we have noted a few suggested clarifications or refinements to the items contained in the April 27 Notice.

HIMA has the following recommendations for accelerating the time frames associated with the national coverage review process:

• *In modernizing the Medicare coverage process, HCFA should focus on the time it takes to fully integrate a new medical technology into the Medicare program, not merely on discrete steps in the process. HCFA should measure (and report on) its performance by measuring the total time it takes to complete the coverage, coding, and payment processes, as well as the various components of these processes.* In addition, HCFA should, within one year of implementation of the April 27 Notice, set forth specific time frames for completing these coverage, coding, and payment processes. Despite the time frames specified in the Notice for certain elements of the national coverage process, the task of bringing a new technology into the Medicare program +and making it available to beneficiaries is too lengthy. The Notice sets forth time frames that will take close to a year for the most non-controversial reviews, and at least two (and perhaps three or more) years for more controversial matters. Patients deserve prompt access to needed medical treatments. It is unrealistic to expect this process to consume this much time after a technology has been approved or cleared for marketing by the U.S. Food and Drug Administration. Measuring performance (and making the findings available to the public) should serve as a management tool

to help ensure that the coverage, coding, and payment processes are coordinated and proceed in a timely way. Further, we believe that, once HCFA has had experience with implementing the new coverage process, it will be able to set specific time frames for the coverage, coding, and payment processes.

• *HCFA should specify a 45-day period during which it will determine whether to accept a formal request for a national coverage decision.* The Notice currently specifies that the national coverage review process does not begin until a formal request has been filed by a requestor and accepted by the agency. Acceptance by the agency starts a series of time frames. The Notice states that: "If we determine the request is adequately supported, we will accept the request and begin our review process." The Notice provides no certainty concerning how long it will take the agency to review a formal request and determine whether or not it is in order. We suggest that the formal submission of the request should trigger the beginning of the review process and the time frames set forth in the Notice. Further, we suggest that the agency specify a period-up to 45 days, one-half the current 90-day period set forth in the Notice-to determine whether the request is in order. If the request is accepted, all time frames specified in the Notice should be initiated from the date the request was received by the agency. If the request is not accepted during the 45-day period, the review process time frames are not begun. This is the current practice used by the Food and Drug Administration in considering whether to accept medical device Pre-Market Applications for filing.

• *HCFA should take steps to ensure that any referrals it makes for MCAC review or for technology assessments are completed within time targets specified by the agency.* While the Notice provides certain elements of the review process with time frames, none are specified for the time an MCAC review will take. (The Notice states only that HCFA expects the review will proceed "as expeditiously as possible.") In addition, the Notice informs the public that technology assessments may take anywhere from 90 days to a year, and perhaps longer. When HCFA makes a referral, it should specify a time frame within which it expects a response.

• *HCFA should clarify the situations under which MCAC may request a technology assessment.* The Notice indicates that both HCFA and MCAC have the prerogative of requesting a technology assessment. We are concerned that situations might arise where both HCFA and MCAC might request assessments, or disagree with respect to the need for an assessment. Our reading of the Notice is that MCAC might well request a technology assessment during the course of its review of a technology, and then resume review once a technology assessment has been completed. Given the time that might be associated with such assessments, and their impact on the time it might take to complete the coverage review process, we request more clarity on the circumstances under which referrals for technology assessments will take place.

• *HCFA should streamline the coding and payment processes associated with the review of new technologies by assigning temporary procedure codes (where no codes exist).* For example, HCFA could assign a code when a request for a national coverage decision is made and accepted by the agency. HCFA's coverage, coding, and payment processes are not coordinated, and their current operations slow the integration of new medical technologies into the Medicare program. Assigning temporary procedure codes (where none exist) at the start of the national decision making process would eliminate one hurdle to speedy implementation of coverage decisions. The Notice provides 180 days to put in place systems to carry out coding and payment determinations with respect to the newly-covered technology-effectively delaying beneficiary access after a national coverage decision has been made. We also have concerns that the separate processes by which HCFA makes decisions on which procedure code is appropriate for a given technology, and which payment level is adequate, are in need of modernizing as well.

• *HFA should avoid unnecessary delay in making covered technologies available to beneficiaries by eliminating the 180 day period the Notice provides to implement national coverage decisions.* Coding and payment matters can be handled more expeditiously than provided for in the Notice. There is no need to delay patient access to a new medical technology for a period that will take more than six months (and more likely eight or nine months) after the agency has determined that it is "reasonable and necessary" and should be covered. HCFA's coverage, coding, and payment regimes should be streamlined, operate concurrently, and provide more timely beneficiary access to covered services. Instead of delaying beneficiary access to newly-covered technologies for 180 days to allow for new payment systems to be put in place, HCFA has tools available to make the covered items available as soon as the coverage determination has been made. For example, HCFA could take action that would permit contractors to hold claims for newly covered items and bill later when new payment systems have been established. It could also make use of new methods

for determining interim payment amounts to reimburse providers (in place of current inadequate methods which include gap fill and arbitrary assignment into existing payment categories, like DRGs) until final payment levels have been set. Further, it could require contractors to accept temporary codes and process them manually until new systems become available.

In addition, HIMA recommends that the coverage process described in the April 27 Notice be amended to address the following:

• *HCFA should recognize that the descriptions set forth in the April 27 Notice serve as a starting point for modernizing the coverage process, and that revisions need to be made that make more firm commitments to the public.* The Notice contains a general description of the coverage process, but does not really define it. The Notice's descriptions of the coverage review process and its component parts repeatedly use terms like "generally," "usually," or "ordinarily" to explain operational procedures. Firm commitments are not made. We believe that the process should be made more certain and predictable, and that the lack of commitment that characterizes the April 27 Notice should be replaced with more certain processes as the agency responds to comments, such as these, and as it gains experience.

• *HCFA should permit those requesting national coverage decisions to meet early in the product development process to reach collaborative agreements with the agency as a means to expedite decision making.* We believe that HCFA should build into the national coverage process the opportunity for a product sponsor to meet with coverage policy staff for the purpose of reaching agreement on the requirements needed to secure Medicare coverage approval (e.g., requirements regarding the type of evidence the product sponsor may develop, as well as protocol design). This meeting should be available early in the product development process-prior to FDA approval or clearance-in order to lay out the agency's requirements for securing approval in the coverage review process. We recognize that these meetings will require the agency to commit its resources, but we believe those resources will produce savings down the road as the agency reviews the information produced by the requestor.

• *Reforms in the coverage decision making process should be made applicable to local medical review policies developed by local and regional contractors (i.e., carriers, intermediaries, DMERCS, and Medicare Integrity Program contractors).* Medical device innovation is characterized by continuous, incremental improvements, based on the feedback of medical professionals who use these technologies in actual clinical settings. The local coverage process is especially well suited to evaluating innovative medical technology. While we recommend that reforms be made at the local level, we need to emphasize that the current ratio of local to national decisions serves the system well. This emphasis on local decision making offers important flexibility to the system that needs to be preserved. Further, local decision making is in some ways more economical to administer and helps to ensure that new technology does not diffuse until it is well accepted. We believe that HCFA should require that reforms at the national level that are designed to make the decision making process more open and understandable to the public be implemented at the local and regional levels as well. For example, the public should be able to make suggestions for local coverage determinations, time frames for review should be put forth, the review process should permit public participation, and the rationale for decisions should be made available (with contractors responsible for responding to public comments received). In addition, meetings of local carrier advisory committees should be opened to the public (including providing advance notice of meeting dates and agendas). Further, in situations where some or all of the contractor medical directors jointly create working groups, their discussions should be open to the public. Any working groups should be specifically identified on the agency's web site, and meeting agendas for the groups should be posted as well. Proposed policies developed by joint working groups should be taken through the local policy development process. HCFA should require these openness, transparency, and public participation objectives for the local and regional coverage process as it negotiates and finalizes contracts with carriers, intermediaries, and DMERCs each year. We would expect that contractors would seek to achieve these objectives in equally effective—yet diverse—ways, tailored to local conditions. We also believe that HCFA should provide access to these contractors (and their procedures) on its web site.

• *HIMA requests the following actions to clarify our understanding of the Medicare coverage process:*

• *HCFA should specify a time period-no longer than 60 days-during which it will make a coverage decision after receiving a technology assessment.* The Notice specifies that HCFA will make a decision within 60 days of receiving advice from MCAC; no comparable time period is set out for decision making should HCFA request and receive a technology assessment directly. We believe that this was an oversight, and

we suggest that HCFA clarify the time frame for making coverage decisions after receiving a technology assessment.

• *HCFA should make it clear to its contractors that their authority for making local and regional coverage decisions are not pre-empted by the initiation at the national level of the coverage decision making process.* Most coverage decisions are made at the local and regional levels. Current policy is that Medicare's local and regional contractors have authority to make coverage decisions absent an extant national policy. In order to avoid confusion and to guarantee that contractors carry out their responsibilities in a timely way, HCFA should make this policy clear to its contractors. Given the long times associated with national decision making, it is important to ensure that the local and regional processes remain responsive to requests for coverage decisions.

• *HCFA should provide additional time for the public to prepare evidence for MCAC.* The Notice specifies that all evidentiary presentations before MCAC must be submitted in writing at least 20 days prior to MCAC meetings. MCAC meetings themselves are announced in the Federal Register 30 days prior to meetings. This leaves only 10 days for an interested party, who may be a product sponsor, to prepare and submit material for MCAC consideration. We believe that this short time period was unintended, and we urge HCFA to provide a more reasonable time period in its place.

• *HCFA should provide further guidance to the public on how to participate in the coverage process. In particular, HCFA should consider expanding the Notice in the following areas:*

• *Notice of a request for technology assessment.* When HCFA seeks a technology assessment, posting a notice on its web site would allow interested parties to comment on the scope and direction of the request, submit information that may be useful in the assessment, or even conduct studies or investigations that will prove useful in parallel to the assessment.

• *Notice of issues on which HCFA would like input.* When HCFA initiates its review of a service or item for coverage, it should do more than acknowledge that it has received a request. Through a posting on its web site, the agency should let the public know what data it has, and where it has questions that it would like answered. By doing so, interested persons will be able to help by supplying information that addresses the agency's concerns.

• *The use of interactive techniques for collecting public input.* HCFA should describe its plans for using town hall meetings and other techniques for encouraging interactive dialogue on the complex issues that surround coverage decision making.

• *A commitment to respond to comments.* Replies to comments accomplish two objectives-they educate the public regarding how the agency resolves the issues, and they encourage public participation by showing that the agency is listening.

• *A description of the process HCFA plans to use to develop guidance documents.* While the agency may be planning to address the process for developing guidance documents in another vehicle, we did not want to miss the opportunity to observe just how important it will be for the agency to spell out the public process it will use to develop these documents. FDA has a good model, which it has published (see 62 Federal Register 8961, February 27, 1997).

• *National Non-Coverage Decisions should be issued only where clear evidence exists to support this action.* HCFA should understand that early in the life of a new technology, the quantity and quality of information that is available regarding the technology may be in short supply, and not sufficient to support a favorable national coverage decision. HCFA should refrain from making a National Non-Coverage Decision in these instances, because such a decision will prevent local and regional contractors from covering the technology and developing useful information concerning its impact on patient well being. HCFA should only issue National Non-Coverage Decisions where it has an adequate information base to support this course of action. Thank you for considering these suggestions. We hope to see a revised Notice published soon that reflects the comments you have received on this important matter. In addition, we believe that HCFA should pursue formal rulemaking on this matter, after a period of time-we suggest a two-year period beginning with the date of publication of this Notice-during which it gains experience managing this new national coverage process.

Sincerely yours,

TED R. MANNEN
Executive Vice President
Health Care Systems

ONCOTECH, INCORPORATED
IRVINE, CALIFORNIA
October 14, 1999

Chairman Bill Thomas
House Ways & Means Subcommittee on Health
Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Thomas,

As you recall, I was privileged to provide testimony at the hearing which was conducted by the Ways & Means Committee on Health on April 22, 1999. Following the hearing, the Committee drafted and introduced legislation, specifically HR 2356, to redress the issues raised during the hearing. I have had an opportunity to review HR 2356 in detail and wish to submit the following observations.

One of several issues addressed by the legislation relates to the length of time required for a carrier denial to be reviewed by an administrative law judge. Currently, an average of 564 days is required. The legislation reduces this period to 90 days. Substantively, this is a dramatic improvement in the timeliness of decisions. Medicare patients should not be exposed to an inappropriate denial of benefits simply by the length of time it takes to proceed through the appellate process.

A second issue addressed by the legislation relates to the internal bias found within the carrier in favor of the local medical director's decision. Our experience, which has been shared by numerous other companies, has found that the early phases of the appellate process which are administered and implemented by carrier employees, are not objective. This phenomenon is not substantially different from that found within HMOs and other commercial carriers. As you know, within the last 120 days, both the Senate and the House of Representatives have passed legislation to provide independent, objective appellate review of claims denials. HR 2356 provides Medicare patients with the same access to independent review that the legislation mentioned above provides to patients who are commercially covered. It does this by allowing providers and beneficiaries to bypass the internally controlled carrier appellate steps and go directly to an administrative law judge. In our judgement, the ability to move an issue directly to an administrative law judge ensures that patient care issues will be determined in a fair and unbiased environment.

A third issue addressed by the legislation requires that a policy decision made by a local medical director be subject to oversight, review and change by an administrative law judge. Currently, local medical directors are not required to acquiesce in the decision of an administrative law judge vis-a-vis their local medical policy. Local medical directors claim that an administrative law judge decision is limited exclusively to the patient or patients upon which the ALJ is reaching his conclusion, thereby placing their local medical policy above appellate review. This practice leaves local medical directors in a position of absolute power. HR 2356 vitiates this practice, removes the absolute power exercised by local medical directors under the current legal structure and prevents the burdensome and timely re-litigation of inappropriate local medical policies.

For the reasons stated above, it is essential that HR 2356 be enacted. Medicare beneficiaries have a right to independent review that is characterized by objectivity, power to change errors and timeliness. This bill clearly establishes these rights on a clear, legal foundation.

Personal regards,

FRANK J. KIESNER, J.D.
President & CEO
Oncotech

Statement of American Medical Association

The AMA and national medical specialty societies have repeatedly advocated to HCFA that standards of openness, accountability, timeliness, and evidence-based decisionmaking be imposed on the local coverage policy development process to ensure that local policies reflect the best available clinical and scientific evidence.

The physician community has also repeatedly advocated to HCFA that at both the local and national levels its coverage policy process be separated from its fraud and abuse and program integrity activities.

Also, we have advocated that the new process for making national Medicare coverage decisions using the Medicare Coverage Advisory Committee (MCAC) be set up to meet the needs of practicing physicians and patients for clear guidance on covered benefits, instead of being driven by the marketing strategies of manufacturers and suppliers.

The HCFA Notice of April 27 announcing its new coverage policy process falls short of these objectives in several respects:

- The Notice gives no attention to the problems with local policies established by the Medicare carriers. HCFA continues to promulgate a view that if it sets up an open, accountable, timely, and evidence-based national coverage process, then this will somehow "trickle down" to the local level.
- The MCAC process meets the objectives of openness, timeliness, accountability, and evidence-based decisions in a number of respects. The Notice strongly emphasizes the use of a "formal reques" process for getting topics before the MCAC, however. The AMA has grave concerns that such a process, which seems to be modeled after the Food and Drug Administration (FDA) process, will ensure that large entities with significant resources and FDA experience will dominate the Medicare coverage agenda. Physician organizations and beneficiaries with concerns about Medicare coverage of nursing home visits, mental health care, lab tests, and palliative and end-of-life care, for example, may have a difficult time getting HCFA's attention.
- The only avenue for physicians and patients to pursue besides the new MCAC is the current Medicare appeals process. Local determinations must be addressed through this process one claim at a time, with no remedy for poorly constructed local policies that are aimed more at preventing fraud than ensuring delivery of necessary medical care. This process is also outrageously lengthy and unfair to physicians and patients.

Mr. ROSEBROUGH. Thank you.

Dr. PLESTED. Thank you.

Mr. KIESNER. Thank you.

Chairman THOMAS. Thank you, and the Subcommittee stands adjourned.

[Whereupon, at 3:36 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of Angela Loavenbruck, American Academy of Audiology, McLean, Virginia

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to submit the testimony of the American Academy of Audiology for inclusion in the printed record of the Hearing on Medicare Coverage Decisions and Beneficiary Appeals. I am Angela Loavenbruck, D.Ed., Chair of the Government Reimbursement Committee of the American Academy of Audiology (AAA). With 7,000 members, the AAA is the major national professional association representing audiologists in the United States. We wish to submit this statement on behalf of the 13,000 practicing audiologists and the 28 million Americans who suffer from hearing disabilities.

The AAA would like to add its voice to the chorus of those who believe that glaring inconsistencies in coverage decisions between different regional and local carriers is a serious and growing problem. The Health Care Financing Administration's (HCFA) apparent acceptance of these inconsistencies is bad policy and unfair to both Medicare beneficiaries and Medicare providers.

The particular problem that audiologists face is the refusal of some carriers to cover audiometric diagnostic tests that result in identification of hearing loss for which there is currently no medical or surgical treatment possible. Medicare Part B covers diagnostic testing to determine the cause of a hearing loss, but it does not cover "hearing aids and examinations therefor." 42 U.S.C. § 1395y(a)(7); 42 C.F.R. § 411.15(d). Thus, HCFA has determined that diagnostic testing should be covered where it is needed to determine whether medical or surgical intervention is called for; it should not be covered where testing is performed solely for the purpose of fitting a hearing aid. According to the Medicare Carriers Manual, coverage should

be denied where "diagnostic services are performed only to determine the need for or the appropriate type of a hearing aid" and where "the medical factors required to determine the appropriate medical or surgical treatment are already known by the physician or are not under consideration." Medicare Carriers Manual § 2070.3 (emphasis added).

Contrary to HCFA's announced policy, some carriers routinely and automatically deny reimbursement for any diagnostic testing that identifies hearing loss which can only be treated with the fitting of an amplification device. Coverage is denied even though the nature, extent and cause of hearing loss is unknown prior to the tests. Just as some carriers deny coverage of a prostate-specific antigen test (PSA test) if the resulting diagnosis is an enlarged prostate rather than cancer (*See* testimony of Dr. William G. Plested, III on behalf of the American Medical Association), some carriers deny coverage of audiometric diagnostic tests if the resulting diagnosis cannot be treated with medical or surgical intervention.

When a patient complains of hearing loss, the only way to determine the nature, extent and cause of the hearing loss is for a qualified audiologist to perform a battery of audiometric diagnostic tests. Any reputable medical textbook will say that there is simply no other way to make a sound diagnosis. This is the standard of care for diagnosis of hearing loss. That Medicare will cover a service that represents the standard of care for some kinds of hearing loss but not for others seems discriminatory. To reimburse for any medical test depending upon the outcome also may create an incentive to skew the results of that test. For audiologists, a carrier policy that denies coverage of diagnostic tests if the tests do not discover a medically or surgically treatable condition can have a serious impact on their practice.

The AAA also agrees with other witnesses that Medicare beneficiaries should be able to appeal carrier coverage policies, not just individual denials of claims. The AAA believes that HCFA must exercise some oversight over the policy decisions of carriers. It is inconceivable to us that the beneficiaries of one of the federal government's largest programs should have no recourse to appeal policy decisions made by private companies administering the program. In addition, we believe that Medicare providers should also be given the right to appeal carrier policy decisions.

Thank you for this opportunity to share our views. The American Academy of Audiology would be pleased to answer any questions you may have. We would also be glad to work with the Subcommittee and with HCFA to develop a solution to the specific problem of inconsistent carrier policies regarding audiology diagnostic testing, as well as solutions to the larger issues raised at the hearing.

Statement of American College of Physicians-American Society of Internal Medicine

The American College of Physicians-American Society of Internal Medicine (ACP–ASIM), representing over 115,000 physicians and medical students, appreciates the opportunity to submit a statement for the record to the Committee on Ways and Means Subcommittee on Health on how the Health Care Financing Administration (HCFA) makes decisions regarding Medicare-covered services and what opportunities exist for beneficiaries and physicians to appeal those decisions. ACP–ASIM applauds the Subcommittee for holding a hearing to analyze the processes available to seniors and physicians to appeal coverage decisions under Medicare, particularly those made by Medicare carriers.

ACP–ASIM has reviewed the national coverage process developed by HCFA and published as a notice in the April 27, 1999 Federal Register. ACP–ASIM will be glad to share any comments it has regarding HCFA's national coverage process with the Subcommittee.

However, HCFA's coverage process fails to address local coverage decisions. This is especially noteworthy since HCFA recently confirmed that approximately 90 percent of all coverage decisions are made at the local Medicare carrier level. HCFA currently allows its carriers broad latitude in making local coverage decisions. While HCFA touts its national coverage process as more "open, understandable, and predictable," the current process for making local coverage decisions continues to be somewhat closed, ambiguous, and unpredictable. ACP–ASIM believes that the process by which Medicare carriers make local coverage decisions needs to be reformed.

LOCAL COVERAGE DECISIONS

Local coverage decisions take the form of local medical review policies (LMRPs). HCFA requires that LMRPs be developed in consultation with a local carrier advi-

sory committee (CAC). Each state maintains a CAC that is comprised of one physician representative per each major medical specialty. A Medicare carrier medical director (CMD) must distribute a proposed LMRP to the CAC before implementing it as carrier policy. CAC representatives have a minimum of 45 days to gather comments from their respective specialties. The CMD has full discretion in determining how to incorporate comments received from the CAC during the comment period. The LMRP takes effect 30 days after being published by the carrier.

Section 7501.2 of the Medicare Carriers Manual (MCM) clearly states that it is the responsibility of the CMD to determine when an LMRP is needed. The CMD is instructed, but not limited to using the following sources:

- Carrier data, such as reports identifying a significant utilization of an item/service in the past year;
- National claims history;
- Information obtained from State medical and specialty societies or individual physicians;
- Recommended model policy developed by national or regional medical director workgroups;
- LMRPs established by other carriers in reaction to abusive or aberrant practices, in order to proactively address the potential migration of these practices;
- Complaints from beneficiaries; and
- Recommendations from other sources, such as Office of Inspector General reports, fraud unit, etc.

The focus of LMPRs varies. A CMD can use an LMRP to determine whether an item/service is a covered benefit by the Medicare program. Further, an LMRP can determine the clinical conditions under which a covered service will be paid for by the Medicare program.

Problems with the LMRP Process

In reality, it is extremely difficult for physicians to keep track of LMRPs. Requirements are communicated to physicians in a disjointed and ineffective way. CMDs update LMRPs that determine the conditions under which a covered service is paid for by periodically publishing additions and deletions to the list of acceptable clinical conditions, usually in the form of diagnosis codes. Typically, only the changes are listed. The original policy is rarely updated and published in its entirety. The result is that individual practices have to update the original policies in their files to maintain accurate information, which makes it virtually impossible for physicians to learn LMRPs. Even the most well-informed physicians have difficulty keeping apprised of changing LMRPs.

ACP–ASIM is not arguing that all coverage decisions and policies should be national. The College supports local physician input into LMRPs. CMDs, in conjunction with CACs, play a key role in ensuring that local Medicare policies are fundamentally related to what the local medical community views as appropriate standards of medical practice. The LMRP process should be reformed, however. This could be accomplished through structural improvements to the CAC process and by identifying "best practices" of the existing State CACs.

Recommendations

1. HCFA Should Separate Local Coverage Decisions From Program Integrity functions. HCFA's Office of Clinical Standards and Quality should oversee carrier LMRP issues.

Section 7501.2 of the MCM states that "LMRP(s) is primarily a program integrity tool" and that "it is generally developed to specify criteria that describes whether the item/service is covered and under what clinical circumstances it is considered to be reasonable, necessary, and appropriate." Further confirmation that LMRPs focus on program integrity is that Section 7503 of the MCM, which pertains to CACs, instructs the CAC co-chair to send copies of CAC meeting minutes to HCFA's Program Integrity Group/Contractor Management Group with the Office of Financial Management at the agency's central office.

It is inappropriate for coverage decisions to be made based on whether they save money. Denying a item/service as a covered benefit or restricting it's a coverage to a limited number of clinical conditions because of cost considerations and/or because of perceived or potential overutilization is unfair to beneficiaries. It is problematic that CMDs are primarily accountable to the Program Integrity Group within HCFA's Office of Financial Management when making coverage decisions. Beneficiaries' interests would be best serviced if the office within HCFA that focuses on

quality of care was the one that decides which items/services are reasonable, necessary, and appropriate.

2. Carriers should provide a 60-day public comment period for all proposed policy changes instead of the current 45-day comment period.

The current comment period is too short for medical societies to make informed judgments and comments on policy changes. This is a problem particularly in rural states where the size of the medical society staff may be limited.

3. At the conclusion of the comment period, the carrier should state, in writing, its reasons for accepting or rejecting the comments in framing the final policy.

All CAC members should receive the carriers rationale for adopting policy changes, and the public should receive this information on request. Just as the Administrative Procedures Act requires HCFA and other federal agencies to respond to comments made on its proposed rules, so too should carriers have to provide an explanation of why they have adopted a particular policy. In this way, the medical and patient community will know why the carrier is pursuing a particular course of action. In addition, educating physicians and their staffs about the policy change would further the goal of adopting correct policy and relieve carriers of administrative burdens that result from physicians misunderstanding policy changes.

4. HCFA should provide "best practices" guidelines to CMDs so they can incorporate them into their CAC process.

ACP–ASIM is encouraged that HCFA has contracted with the consulting firm of PricewaterhouseCoopers (PwC) to make recommendations to improve the effectiveness and the efficiency of the LMRP development process. As a part of its contract, PwC is to identify "best practices" that could be used to improve local policy development as HCFA attempts to standardize the process nationwide.

ACP–ASIM informally polled its members involved in State CACs to and came up with the following examples of effective CAC processes:

- The Wisconsin carrier continues to work with the CAC member representing the specialty or specialties most affected by a proposed LMRP after the conclusion of the 45-day comment period and before implementing it by publishing it in its Medicare Bulletin. This additional step in the decision-making process enables the carrier to improve the proposed LMRP by allowing further input from relevant specialties, without occupying the time of the entire CAC. This type of increased interaction results in more thoughtful LMRPs and is consistent with the intent of the CAC process. Further, the carrier-physician relationship is enhanced by carrier efforts to work collaboratively with the physician community.
- The CMD that co-chairs the California CAC extended the comment period for 45 to 60 days.
- The Rhode Island CMD sends draft LMRPs to CAC members before the meeting but begins the 45-day comment period on the meeting date (HCFA requires CACs to provide a 45-day comment period that begins when the draft LMRPs are sent out to CAC members).

At a minimum, each of these practices should be adopted nationwide.

5. There needs to be a process for fine tuning LMRPs after they are implemented. The lack of an established process to modify existing LMRPs forces physicians to seek changes in a disjointed manner.

There is no standard way for physicians to appeal LMRP coverage decisions, both those that determine whether an item/service is covered and those that indicate the clinical circumstances in which an item/service is considered reasonable and medical necessary. There needs to be a way to correct misguided LMRPs that are hurried through a process that is not conducive to broad input.

There should be a formal mechanism that allows physicians (for themselves and on behalf of their patients) to recommend changes to LMRPs—whether appealing a coverage decision or altering an LMRP that restricts the conditions in which a covered service will be paid. Recommended changes should go back to the CAC. If the LMRP is further disputed, HCFA's Office of Clinical Standards and Quality should intervene to ensure that beneficiaries are not being denied medically necessary services or being inappropriately forced to pay for them out-of-pocket because of an incorrect LMRP.

Beneficiaries are often saddled with additional out-of-pocket costs for items/services that are not covered and when coverage is inappropriately restricted to a limited number of clinical conditions. In cases were the item/service is covered for only a specific conditions, the physician must find a condition, indicated by a diagnosis code(s), that fits the patient and will be covered. Physicians can currently ask the

CMD to expand the list of conditions that merit coverage. Acceptance or rejection of these recommended policy changes is left solely to the discretion of the CMD. The HCFA central office generally stays out of this area. However, the Program Integrity Group within the Office of Financial Management, and not the physicians on the Office of Clinical Standards and Quality staff, would intervene if HCFA got involved. Clearly, the latter would be a more appropriate arbiter of these issues.

6. Carriers need to assess the financial/cost-benefit impact of the LMRPs that they choose to implement in a systemic way.

Although LMRPs are generally implemented to restrict the situations in which covered services are paid, carriers should be able to determine the overall financial impact of an LMRP. A carrier should collect data on the number of claims pertaining to a denied service covered by an LMRP that are appealed and how often denials are overturned on appeal. It is wasteful to implement a restrictive LMRP that is to save money when the cost of manually reviewing appealed claims outweighs any savings generated by initial denials.

For example, Transamerica Occidental Life Insurance Co., the Medicare carrier for Southern California, maintains LMRPs that limit coverage of laboratory tests such as blood counts, blood glucose, and serum magnesium to a specific list of conditions, indicated by diagnosis codes. Limiting coverage of tests whose use is widely indicated and clinically accepted for the purpose of program integrity is disruptive for physicians and their patients. Adjudicating claims that are appealed after originally being denied because of restrictive LMRPs is likely to actually increase costs if a significant number of denials are overturned on appeal.

7. HCFA has a responsibility to inform beneficiaries that LMRPs that deny coverage of an item/service or restrict coverage to specific patient conditions will cause their out-of-pocket medical expenses to increase.

LMRPs with a program integrity bent have financial implications for beneficiaries. Physicians are forced to strike a balance between ensuring that their patients receive all items/services that are medically necessary and minimizing their patients' out-of-pocket costs.

The simple presence of a LMRP limiting coverage increases the likelihood that patients will refuse items/services. Physicians must ask patients to sign an advanced beneficiary notification form (ABN), in which the patient agrees to pay for the item/service if Medicare denies payment, if they are uncertain as to whether Medicare will pay for the item/service under the circumstances. Difficult-to-learn LMRPs frequently prevent physicians from knowing when Medicare will cover an item/service. Patients are further disadvantaged as those who cannot afford to pay for an item/service out of pocket may forgo the treatment.

Model LMRPs

Ideas for LMRPs are sometimes derived from "model" LMRPs that are developed by working groups of CMDs. CMDs from around the country periodically develop a policy template on an issue(s) that a CMD(s) thinks needs to be addressed. HCFA only reviews these model policies to make sure that they do not contradict national Medicare policy. Individual CMDs can then run the model or a variation of the model through its State CAC for implementation. Currently, national medical specialty societies and other interested parties are generally unable to have input into the development of "model" LMRPs.

Recommendation

National medical societies should have input into "model" LMRPs developed by "working groups" of CMDs for the purpose of being implemented through local CACs.

A working group of CMDs should involve relevant medical societies when formulating a model policy. This type of collaboration will result in more suitable LMRPs and better prepare national medical societies to target educational efforts toward members.

It is a disservice to beneficiaries and providers to allow model LMRPs developed by a regional or national workgroup of CMDs to become de facto regional or national policies. Model LMRPs have the potential to become national policies if they are implemented throughout the country, with the only difference being changes made by the State CAC. It is inappropriate for HCFA to permit model LMRPs that are initiated by a few CMDs whose focus is program integrity become the equivalent of a national policy.

For example, a workgroup(s) of CMDs has drafted at least 15 model LMRPs for clinical laboratory tests. Many of these models were implemented by CMDs through their CACs because of perceived overutilization or because of potential overutilization. As a result, it is likely that a model(s), or a variation of that model(s), has been implemented in many States. We cannot definitively say that every carrier has an LMRP in place for a specific laboratory test or even identify how closely the existing LMRPs track with the model because HCFA currently fails to keep track of the LMRPs maintained by each carrier.

The Balanced Budget Act of 1997 directed HCFA to convene a negotiated rulemaking committee to develop uniform coverage and administrative policies for clinical laboratory tests. HCFA's approach to this committee provides some insight into agency's view of the model LMRPs for laboratory tests. After the negotiated rulemaking committee selected the laboratory tests for which it would develop national coverage policies (now being called "coverage determinations" as they were not derived from the national coverage process that HCFA published in the April 27, 1999 Federal Register), some committee members suggested using existing model LMRPs as a starting point. HCFA, a member of the negotiated rulemaking committee, rejected that suggestion stating that national coverage policies (determinations) needed to be held to a higher standard of scientific evidence. If HCFA is not fully comfortable with using CMD workgroup-developed model LMRPs as a template for national policy, it is certainly inappropriate to allow model policies to in effect become national, with only minor tinkering by State CACs.

Conclusion

ACP–ASIM believes that adoption of the recommendations included in this statement, and recapped below, will ensure that beneficiaries receive all medically necessary services that are provided under appropriate clinical conditions

1. HCFA Should Separate Local Coverage Decisions From Program Integrity functions. HCFA's Office of Clinical Standards and Quality should oversee carrier LMRP issues.
2. Carriers should provide a 60–day public comment period for all proposed policy changes instead of the current 45-day period.
3. At the conclusion of the comment period, the carrier should state in writing, its reasons for accepting or rejecting the comments in framing the final policy.
4. HCFA should provide "best practices" guidelines to CMDs so they can incorporate them into their CAC process.
5. There needs to be a process for fine tuning LMRPs after they are implemented. The lack of an established process to modify existing LMRPs forces physicians to seek changes in a disjointed manner.
6. Carriers need to assess the financial/cost-benefit impact of the LMRPs that they choose to implement in a systemic way.
7. HCFA has a responsibility to inform beneficiaries that LMRPs that deny coverage of an item/service or restrict coverage to specific patient conditions will cause their out-of-pocket medical expenses to increase.
8. National medical societies should have input into "model" LMRPs developed by "working groups" of CMDs for the purpose of being implemented through local CACs.

Thank you for the opportunity to submit this statement for the record. We look forward to working with the Subcommittee to ensure that HCFA addresses the deficiencies in the way local coverage decisions are made by Medicare carriers.

Statement of American Gastroenterological Association, Bethesda, Maryland

I. BACKGROUND

The American Gastroenterological Association ("AGA") is an organization of more than 10,000 physician clinicians, researchers and educators who specialize in the treatment of digestive disorders. The AGA serves its physician and scientist members and their patients through advocacy; supporting members' practice and scientific needs; and by promoting the discovery, dissemination and application of new knowledge, leading to the prevention, treatment and cure of digestive diseases.

The AGA appreciates this opportunity to offer the following Statement to the House Ways and Means Subcommittee on Health, for consideration at its April 22, 1999 Hearing on Problems with Medicare Coverage Policy Decisions. The AGA

Statement focuses on the following two areas: ineffective Medicare coverage for colorectal cancer screening; and inappropriate Medicare carrier interpretation of what constitutes a physician "consultation."

II. SPECIFIC COMMENTS

A. Ineffective Medicare Coverage For Colorectal Cancer Screening

Colorectal cancer, or cancer of the colon or rectum, is the second leading cause of cancer-related death in the United States—some 56,600 Americans will die of colorectal cancer in 1999. When skin cancer is excluded, colorectal cancer is the third most commonly diagnosed cancer for both men and women in the United States. Approximately 129,400 new cases will be diagnosed during 1999. For men, colorectal cancer follows prostate and lung cancers in frequency; for women, it follows breast and lung cancers.

The risk of developing colorectal cancer generally increases with advancing age. African Americans are more likely than whites to be diagnosed with this disease and are more likely to die of it. Other major risk factors include having inflammatory bowel disease, a family history of colorectal cancer or colorectal polyps, and certain hereditary syndromes. Additional conditions contributing to increased risk for colorectal cancer include a personal history of colorectal cancer or polyps or of ovarian, endometrial or breast cancers.

Currently, screening for colorectal cancer lags far behind screening for other cancers, perhaps because the effectiveness of colorectal cancer screening has only recently been documented. In a 1997 survey sponsored by the Centers for Disease Control, only 41% of adults aged 50 and older had ever had a sigmoidoscopy or proctoscopy (an earlier and now less frequently used procedure) for screening or diagnostic purposes, and only 29% of respondents reported having had one within the past 5 years. Of the survey respondents, 39% of adults aged 50 and older reported ever having a fecal occult blood test using a home kit, and only 19% reported having this test in the preceding year.

Survival is greatly enhanced when colorectal cancer is detected early and appropriate treatment provided. Despite the availability of effective screening tests, colorectal cancer screening is underused. Studies show that only 37% of colorectal cancers are diagnosed at a localized stage. When colorectal cancer is diagnosed at a localized stage, death rates are low: only about 9% of these patients will die within 5 years. Once the disease has progressed to a regional stage, about 34% of patients will die within 5 years. When the disease is diagnosed at an advanced stage (has spread to distant sites), death rates are high: about 92% of patients will die within 5 years. For African Americans, 5-year survival rates are lower than those for whites, and a smaller proportion of cases are diagnosed at an early stage. Precancerous polyps may be present in the colon for years before invasive cancer develops. Colorectal cancer can actually be prevented by removing precancerous polyps. Reducing the number of deaths from colorectal cancer depends on detecting and removing precancerous colorectal polyps, as well as detecting and treating cancer in its earliest stages.

AGA is greatly concerned that, because Medicare program carriers are given enormous discretion in implementing the national coverage policy on colorectal cancer screening, each individual who is at high risk for developing this deadly disease, either because of family history of familial adenomatous polyposis, hereditary nonpolyposis colorectal cancer and inflammatory bowel disease, may not be provided the opportunity for adequate screening. AGA has received reports from a number of its physicians indicating that coverage for colorectal screenings is being denied by local carriers. Given the above, Congress should urge the Department of Health and Human Services ("HHS") and the Health Care Financing Administration ("HCFA") to monitor more effectively the local carriers' implementation of the national coverage policy for screening of colorectal cancer for high-risk individuals.

B. Inappropriate Medicare Carrier Interpretation Of What Constitutes A Physician "Consultation"

As part of the Medicare physicians' fee payment schedule, HCFA established guidelines in the Medicare Carriers Manual ("MCM") regarding how local carriers should pay for "consultations" and "new patient visits." HCFA notes in the MCM that, for a *consult*, carriers should pay for the initial consultation if the referring physician does not transfer the responsibility for the patient's care to the receiving physician until after the consultation is completed. However, the appointment should be billed as a *visit* when the referring physician, in the original written or verbal referral, transfers the responsibility for treatment to the receiving physician via a request to "evaluate and treat."

HCFA also states in the MCM that: "a consultation is distinguished from a visit because it is done at the request of a referring physician (unless it's a patient-generated confirmatory consultation) and the consultant prepares a report of his/her findings which is provided to the referring physician for (his/her) use in treatment of the patient. A consultant may initiate diagnostic and/or therapeutic services. *However, when the referring physician orally or in writing transfers responsibility of treatment at the time of the request for consultation or referral, the receiving physician may not bill a consult.*" (Emphasis added).

Several local Medicare carriers recently have tried to redefine HCFA's definition of "consult" by restricting payment for the consult fee if the receiving physician provided *any* treatment whatsoever to the patient. In contrast, the carriers would pay for a consult only if the specialist determined that no treatment was needed. One carrier incorrectly tried to assume that, if the receiving physician follows the patient after the initial encounter, it implies that he/she is assuming part of the patient's ongoing care. These efforts thus far have failed to succeed, largely due to input and pressure by physician members of state American Medical Association ("AMA") affiliates.

AGA believes that the local carriers' interpretations of what constitutes a physician consult are faulty and contrary to the above-noted HCFA definitions, as well as AMA's CPT–4 guidelines, which state that "a physician consultant may initiate diagnostic and/or therapeutic services." AGA is greatly concerned that, because Medicare program carriers are given enormous discretion in implementing health care coverage policy, local carriers will continue to deviate from accepted nationally established definitions that apply to physician practice issues, such as what constitutes a consultation. Therefore, Congress should urge HCFA to monitor more effectively how the local Medicare carriers are implementing HCFA's definition of physician "consultation," in order to ensure that any interpretation contrary to the MCM is not permitted.

Finally, AGA members ardently wish to maintain their stellar record of providing high quality services to their patients. They fear that, taken together, over-burdensome paperwork requirements, fear of unwarranted government intrusion into their practices, and ever-decreasing reimbursements may combine to force AGA members to reevaluate their ability to continue practicing at current levels of care. Medicare beneficiaries should not be put at risk because of excessive government intrusion into the practice of medicine in this way. We urge Congress to impress upon HHS and HCFA that the unintended consequences of their actions, as described above, could indeed achieve this undesirable result.

For further information, please contact Michael Roberts, AGA Vice President, Public Policy & Government Affairs, at 301–654–2055.

Statement of American Occupational Therapy Association, Inc., Bethesda, Maryland

The American Occupational Therapy Association represents 60,000 occupational therapists, occupational therapy assistants, and students of occupational therapy. AOTA's mission includes promoting the interests of the profession and its patients in access to quality services which meet social and individual needs. AOTA submits this statement for the record of the hearing on Medicare Coverage Appeals held April 22, 1999.

Occupational therapy is covered under Medicare Part A and under Medicare Part B as an outpatient service. Under both Part A and Part B, occupational therapy is provided based on coverage criteria which allow for the provision of therapy which is "medically prescribed treatment concerned with improving or restoring functions which have been impaired by illness or injury or, where function has been permanently lost or reduced by illness or injury, to improve the individual's ability to perform those tasks required for independent functioning." (Carriers Manual, Sec 2217, Intermediary Manual (Sec. 3101.9) Further, occupational therapy is considered reasonable and necessary only where an expectation exists that the therapy will result in a significant practical improvement in the individual" level of functioning within a reasonable period of time. Where an individual's improvement potential is insignificant in relation to the extent and duration of occupational therapy services required to achieve improvement, such services would not be considered reasonable and necessary and would thus be excluded from coverage by Sec. 1862(a)(1) of the Social Security Act. (Ibid.)

While this of coverage criteria is established by the Health Care Financing Administration (HCFA), their contractors (e.g., fiscal intermediaries and carriers) have authority from HCFA to develop more explicit local medical review policies (LMRPs).

AOTA would like to concentrate this testimony for the record on issues of coverage determinations, denials and allowances based on the use of LMRPs. Created by HCFA contractors with inadequate oversight and little public input from the agency, LMRPs have caused considerable problems for occupational therapy practitioners and their patients. Variations in coverage, which result from the multiple issuances of fiscal intermediaries, are unfair and unnecessary. HCFA could oversee and regulate the activities of its contractors in the medical review area far more than is currently the practice.

AOTA's experience with the variability of these policies and with the more important problem of the limited public scrutiny of the development of these policies requires that we urge the Subcommittee to consider requiring that HCFA provide national coverage guidance which prevents the establishment and use of LMRPs which unreasonably restrict or make unequal beneficiaries' access to their rightful and appropriate Medicare services.

In particular, HCFA should narrow the fiscal intermediaries' latitude in cases where LMRPs contain significant and unsupported deviations from the national medical review guidelines contained in the Medicare Intermediary Manual.

As witnesses before the Subcommittee on April 22 noted, the Medicare contractors have considerable authority to interpret and apply Medicare's requirements. Testimony before the Subcommittee attributed the conveyance of this authority to historical limitations in HCFA staffing and a view in HCFA that there are regional differences in medical care that should not be overruled by national coverage policy.

Based on AOTA's experience, this bow to regional difference has not resulted in better care but rather has hindered appropriate application of the laws, regulations and professional standards which should guide authorization and denial of care.

HCFA should be required to enforce the national standards for these LMRPs to prevent their development and use in ways that arbitrarily impede the ability of occupational therapists to furnish skilled occupational therapy services based on an evaluation of individual need and rehabilitation potential within the reasonable and necessary guidance of the Social Security Act.

AOTA has long been working to achieve consistency in the many and varied LMRPs as well as to assure that the LMRPs are based on standards of best practice and developed in consultation with experts and authorities on the particular benefit in question. HCFA has not, in our view, exercised sufficient oversight and regulation of the activities of its contractors in the medical review area. AOTA believes that the authority and latitude of the fiscal intermediaries or other contractors should be constrained. As AOTA has seen cases in which the LMRPs contain significant and unsupported deviations from the national medical review guidelines contained in the Medicare Intermediary Manual. We believe the LMRPs should be replaced with a broad and open public process to establish more detailed national coverage criteria.

Such national coverage criteria would assure Medicare beneficiaries equal access to services across the nation. National coverage criteria would replace the current situation wherein a "national" policy is sometimes developed by default when contractors "adopt" other contractors' policies, even if those policies conflict with overall Medicare requirements. Thus, an erroneous and improper "national" policy can become established merely by the spread of LMRPs from one contractor to another, by entities that are not publicly accountable, with limited public review and without sufficient intervention or oversight by HCFA. While the Medicare Intermediary Manual does provide LMRP development guidelines, which should include stakeholder participation, AOTA's experience is that these are not always followed.

Furthermore, while AOTA may be able to intervene in some of these, many beneficiaries and beneficiary advocates find that the existence of multiple LMRPs and standards hinder appropriate access to services. We have also found that many LMRPs, especially in the amount, frequency and duration parameters, are so prescriptive as to impinge upon the ability of professionals to provide care that addresses the medical condition, functional level and rehabilitation possibilities of individual beneficiaries.

A national solution is needed to address this national interest.

AOTA understands that the fiscal intermediaries and other contractors have the authority to develop LMRPs to describe when and under what circumstances an item or service(s) will be covered and to clarify or provide guidance on national coverage guidelines. Conferring this discretion upon fiscal intermediaries does not, we believe, vest them with the authority to supplant pertinent statutory provisions, reg-

ulations, and national coverage policies (which include manual issuances) with informal presumptions. Yet HCFA's oversight and willingness to overrule or moderate LMRPs of fiscal intermediaries is limited. AOTA has had many discussions and meetings with HCFA and its intermediaries over LMRPs to try to assure that the process and resulting products adhere to the overarching principles laid out in Medicare law for benefits and coverage criteria. These interactions have met with limited success.

Beneficiaries and providers deserve consistency in the benefits and providers deserve fair guidance in all areas of the country. The reasonableness and necessity of services should not vary significantly from one region to another

At a minimum, HCFA should be required to oversee the development and implementation of LMRPs to assure that coverage policies are:

- Based on practice standards validated by research;
- Constructed and implemented without impinging upon the professional judgement of therapists (or other professionals) in the formulation of care plans tailored to meet the unique needs of individual beneficiaries.
- Lend constructive guidance and provide appropriate information to beneficiaries and providers.

AOTA must also reference the payment limitation of $1500 annually for occupational therapy services imposed by the Balanced Budget Act as another unreasonable and inappropriate limitation on access to reasonable and necessary services by Medicare beneficiaries. While this issue is not directly related to the April 22 hearing agenda, it is another example of policy developed and implemented by HCFA without adequate consideration of current best practice and appropriate medical standards.

AOTA is supportive of any efforts made by HCFA to address coverage consistency. AOTA has nominated an individual to be a member of the new Medicare Coverage Advisory Committee to represent interests of the rehabilitation community in this important area. We look forward to participating in the work of this Committee, when it is constituted and working with HCFA as they publish new guidelines on policy-making and the definition of "reasonable and necessary."

But we urge the Subcommittee to consider the impact on beneficiaries and on the Medicare program's integrity that result from the failure of HCFA to constrain and oversee the activity of contractors in this area. AOTA would urge consideration of moving to national coverage criteria with all due dispatch. LMRPs do not serve their purpose of providing for local differences in medical care and approach. They create multiple problems rather than multiple solutions.

AOTA urges Congress to require moving away from the outdated approach of defining necessity in the current haphazard, patchwork manner.

We would be pleased to work with the Subcommittee to further address these issues.

Statement of Dwight S. Cenac, Chairman of the Board, Home Care Association of America, Jacksonville, Florida

SECTION I—INTRODUCTION

Mr. Chairman and Members of the Committee,

Thank you for the opportunity to offer written testimony on the critical subject of Medicare Coverage Decisions and Beneficiary Appeals. My name is Dwight Cenac and I am the Chairman of the Board of Home Care Association of America (HCAA). HCAA represents several hundred freestanding home health agencies across the United States.

Mr. Chairman, before I offer my written testimony about coverage decisions and beneficiary appeals, let me urge you to schedule hearings (in the next few weeks) on the issue of the Interim Payment System for home health care. At last count, over 2000 home health agencies have been forced out of business, causing the patients of those agencies to be forced into more costly nursing homes, more costly emergency rooms, or worse, left at home without receiving necessary patient care.

While the GAO, MEDPAC and others are conducting studies pertaining to access to home health services, this committee must address the fact that the BBA of 1997 has placed an unfunded mandate on the states. By the federal government placing a per-beneficiary cap on home health care, agencies across the U.S. are filing for bankruptcy and discharging their patients. Clearly this was not the intent of Congress. Mr. Chairman, you were recently quoted as saying that you were the "Guarantor of small business." Mr. Chairman, the majority of home health agencies being

forced into bankruptcy are small businesses. I encourage you to invite several home health agency owners to testify before your committee in the near future regarding the Interim Payment System.

In addition, due to recent press reports regarding privacy issues pertaining to the OASIS data collection effort, it seems possible that HCFA will not be able to comply with implementing PPS for home health care as mandated on October 1, 2000. It is imperative that you ask HCFA Administrator Nancy Ann Min-DeParle if indeed HCFA will be able to implement PPS for home health care on October 1, 2000. It would also be beneficial to ask Administrator Min-DeParle how the implementation of PPS for skilled nursing is progressing.

Mr. Chairman, I understand that your primary concern is adequate access for doctor-certified Medicare beneficiaries, however, it is important to understand that the most recent CBO numbers show that home health care has been cut $48 billion dollars over 5 years. This is far greater of a cut than Congress intended. I believe you were recently quoted as saying that Congress missed the mark regarding the cuts to home health care. Mr. Chairman, statements are one thing, actions are another.

On behalf of the members of HCAA, I urge you hold hearings in the very near future on home health issues including the viability of a co-pay on home health (which seems to be included in the Breaux-Thomas legislation), the impact of the IPS on home health agencies, and the recent data from the CBO that $48 billion has been cut from the home health benefit.

SECTION II—TWO EXAMPLES WHERE THE APPEAL PROCESS FAILED

Example #1

In California, one of the first states targeted by Operation Restore Trust, one home health agency attempted to stand up to HCFA, and has apparently lost its battle to serve its patients. CSM Home Health Services, Inc., is a 10-year-old Los Angeles agency, which has spent more than $100,000 on legal and consulting services to fight its improper Medicare decertification after an ORT survey.

History of the CSM Case

On March 1, 1996, HCFA and the California State survey agency conducted a compliance survey of CSM. Based on that survey, CSM was found not to be complying with eight conditions of participation. HCFA and the California State survey agency conducted a second survey of CSM which was completed on May 30, 1996. On June 26, 1996, HCFA notified CSM that, based on the second survey, HCFA had determined that CSM was not complying with four conditions of participation. On July 25, 1996, HCFA terminated CSMs participation in Medicare.

The first judge in the CSM case, the Honorable John G. Davies (Case No. CV 96–4651–JGD),United States District Court—Central District of California, could find no legal grounds to grant CSM relief, although he definitely wanted to. Judge Davies said of the ORT process, "I think the surveyors—I think CSM Home Services has a case. The evidence that is before me that I have perused, read, considered, leads me to those conclusions. The Surveyors, I had the Impression, were not reticent to wear their power on their cuff and to manifest it and exercise it in ways that are undesirable in today's society. The bureaucracy overreacted once again. That is my view of this case. But, what relief can I give you?"

After Judge Davies was unable to give relief to CSM, the case was referred to Administrative Law Judge Steven T. Kessel. Judge Kessel reviewed the case in which HCFA decertified CSM. In Judge Kessel's October 11, 1996 ruling he stated, "I decide that the Health Care Financing Administration (HCFA) incorrectly determined to terminate the participation in the Medicare program of Petitioner, CSM Home Health Services, Inc. In this case, HCFA asserted that Petitioner failed to comply with four conditions of participation in Medicare. I find that the preponderance of the evidence is that Petitioner complied with all of these conditions." In addition, Judge Kessel states, "In many instances, HCFA rests its allegations on characterization of facts which are not supported by the evidence. In some instances, HCFA asserts that nurses employed by Petitioner failed to discharge specific directives in patients' plan of care when, in fact, the record proves that they did precisely what they were ordered to do. HCFA asserts also that Petitioner failed to conduct a required program evaluation despite overwhelming evidence that Petitioner performed the evaluation."

What follows is a portion of the sworn testimony of one of CSM's key employees. It is given this Subcommittee as a reference point of the type of agency being abused by the unbridled ORT process, as it currently operates. "I, Jean R. Murphy, R.N., have been a registered nurse for over twenty years, a portion of which was served

as an officer and flight nurse in the United State Air Force. I have approximately thirteen years of experience in home health care as an administrator and/or consultant. I am currently administrator of CSM Home Health Services, Inc. I have held this position for four years. CSM has been serving Los Angeles' underserved minority communities since 1985. These communities include the Rampart District, South Central Los Angeles, Koreatown and other primarily minority communities. CSM's clerical and field staff are also primarily minority. CSM staff continued to serve their clients during the 1992 riots under security guards. During the Northridge earthquake, my staff forsook their families to rush to the aid of their patients. One black certified home health aide was present in a board and care facility during the earthquake; and placed several residents under mattresses to protect them as she, herself, braced and quieted their fears.

The CSM Director of Nurses stood in water without power using her cellular phone to try to reach staff and patients to ensure their safety, despite the fact that she, herself, was in peril because the gas supply in her apartment had not been turned off and had been evacuated for fear of explosion. One of CSM's clinical supervisors was carjacked and robbed at gunpoint while she sat in her car solving a patient crisis on her mobile phone.

Another registered nurse, whose husband had driven her to a patient's home after the riots, was shot as they sped away to avoid being carjacked or killed. CSM has undergone Medicare recertification surveys annually since its founding. These surveys have been conducted by the surveyors from the Department of Health Services, who have found only minor deficiencies with CSM's compliance with Medicare Conditions of Participation. CSM responded to these deficiencies with corrective action plans; and there have never been any termination actions initiated against CSM as a result of these minor deficiencies."

HCAA asks this question: When two judges rule in favor of a home health agency, should HCFA appeal the decisions?

HCFA has chosen to appeal Judge Kessel's October 11, 1996 decision. Here is a letter dated January 31, 1997 to HCAA Chairman Dwight Cenac from CSM owner Marianno Velez which states his thought about his ordeal:

"These past few months have been terrible for me, and I fear the burden has gotten the best of me, causing the worst case of depression that I have encountered, so much so that I felt a deep sense of fatigue, a loss of energy, as well as spirit, to continue living from day to day. I share this with you because what happened to me should not happen to anyone else. ... As you probably know already, HCFA has filed their appeal to reverse the ALJ (Judge Kessel's) ruling on CSMs case. And because of our outstanding debt to our lawyers, we have not been able to reply to HCFAs appeal. I am afraid all is lost—for the industry as well—if the ruling is reversed."

Example #2

A recent issue of USA Today detailed the story of Home Health and Hospice Care (HHHC) located in North Carolina. USA Today reported that dozens of state and federal agencies were in on the bust at the eight offices of HHHC on a January morning in 1995. USA Today reported that, suspecting the North Carolina company of billing Medicare and Medicaid services it wasn't providing, the agents seized everything, hauling off 5 million records in trucks borrowed from the local Post Office.

USA Today also reported in this article that fifteen months after the raid, a federal magistrate killed the HHHC case, ruling that the government misrepresented evidence to obtain it's warrants. Three times, the government appealed, but each ruling mirrored the magistrate's ruling: The government had pursued it's case with "reckless disregard for the truth."

Deputy Attorney General Eric Holder has been quoted as saying, "I recognize that at times our approach has been perceived to be heavy-handed." This clearly is an understatement. HCAA suggests that you ask Beverly Withrow, President of HHHC to testify before your committee about this abuse of power.

These are but two examples of the failure of the current appeals system. It is also troubling to me that when an Administrative Law Judge (ALJ) rules in favor of the home health provider, the Administrator of HCFA is given the power to overturn an ALJ ruling (also at the PRRB level). It is imperative that the HCFA Administrator honor the rulings of ALJ's. It is important to note that HCFA believes that ALJ's are not trained or educated on Medicare policy. I urge this committee to ask the HCFA Administrator is she thinks ALJ's are able to render just decisions pertaining to home health care issues. YOU WILL BE SURPRISED AT HER RESPONSE. ALJ's are legal professionals and they clearly understand the issues brought before them. For HCFA to believe that ALJ's are ignorant is just another glaring example of the arrogance of HCFA.

SECTION III—ONE POSITIVE DEVELOPMENT REGARDING THE APPEALS PROCESS

Currently, due to the Provider Reimbursement Review Board's backlog of cases, it takes approximately three years for a case to be scheduled for a hearing. Taking advantage of that fact, some fiscal intermediaries make audit adjustments (some times erroneously) to providers cost which result in recoupment of Medicare dollars with the expectation that the provider will not have the financial staying power to survive while the PRRB case is pending. Subsequently, when the adjustment is reversed by the PRRB, the provider has been forced to operate without the capital of an otherwise reimbursable expense for at least three years.

However, the Office of Hearings (in the Department of HHS) in conjunction with the PRRB established an alternative dispute resolution process for early resolution of pending cases. Office of Hearings staff members were trained as mediators through the HHS Departmental Appeals Board Shared Neutrals program. The initial results of this project were promising, and the mediation pilot will be expanded during f.y. 1999. HCAA applauds HCFA for this cutting edge approach and we request that HCFA invite HCAA to work closely together in the future on this effort.

SECTION IV—CONCLUSION

On the issue of HMO's it is amazing to me that when HMO profits are at stake, Senator Roth of the Senate Finance Committee wrote a letter to Administrator MinDeParle last year regarding his concern; but with home health care, which is a cost-based system, little is being said by the Chairman of the Senate Finance Committee about the IPS for home health care being an unfunded mandate on the states, forcing patients into more costly nursing settings, or worse, patients being left at home without receiving necessary care. I hope that Senator Roth, in concert with Chairman Archer, passes meaningful legislation this year to restore proper funding to the Medicare home health benefit.

I am also concerned that the concept of "reasonableness" has evaporated from HCFA and the fiscal intermediaries. The Provider Reimbursement Manual, Part I Section 2600 states, "For cost reporting periods beginning after December 31, 1973, reimbursement to providers for services to Medicare beneficiaries will be based upon the lower of the *reasonable* cost of providing those services or the customary charges for the same services."

Home health agencies across the U.S. have been under an unrelenting attack by the fiscal intermediaries regarding costs, but these same fiscal intermediaries are not using the concept of reasonableness when auditing these home health agencies.

HCFA must reinstate the "waiver of liability" to home health agencies who are complying with laws and regulations. Home health agencies are paid on a "cost-based" system. Their is no profit in home health care. The "us versus them" mentality (at HCFA the intermediaries and the surveyors) must be replaced by the concept of reasonableness between surveyors, fiscal intermediaries, HCFA and home health providers when dealing with audit and compliance issues.

In conclusion, I would appreciate the opportunity to personally testify before this committee on home health issues in the future. I look forward to that opportunity.

Statement of Medical Device Manufacturers Association

The Medical Device Manufacturers Association (MDMA) appreciates this opportunity to submit comments for the record of the subcommittee's April 22 hearing on Medicare coverage and beneficiary appeals. MDMA is a national trade association based in Washington, D.C. that represents nearly 130 independent manufacturers of medical devices, diagnostic products and health care information systems. As the national voice for the innovators and entrepreneurs in the medical device industry, MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of beneficial innovative products.

Without question, decisions on what services will be covered under the Medicare program are crucial to the health of Medicare beneficiaries and to continued innovations in medical technology. Medicare is the largest payer in the American healthcare system, and private insurers often consider Medicare's decisions as they make their own determinations about covered services. For Medicare patients to benefit from advances in medical technology, the Medicare program must have processes and systems that allow for the adoption of these advances in a timely manner.

MDMA applauds the Health Care Financing Administration (HCFA) for publishing a notice that outlines, for the first time, how HCFA makes national coverage determinations. Although we believe the process set forth in the notice needs further refinement, MDMA believes that the act of publishing this notice is an important first step toward bringing much-needed clarity and openness to the Medicare coverage process. We also commend HCFA for considering the views of industry as HCFA developed this notice.

MDMA hopes, however, that HCFA will entertain constructive suggestions to improve the notice, even though HCFA has not created a formal route for comments thereon. MDMA also looks forward to working with HCFA to fulfill HCFA's promises to develop specific criteria upon which coverage determinations will be made, and to bring transparency and openness to the local coverage policy process as well.

MDMA welcomes this subcommittee's attention to the Medicare appeals process. Medicare should have an adequate and streamlined mechanism to address the claims of beneficiaries with unique circumstances that may necessitate the revisiting of a Medicare coverage determination. Manufacturers should also have a process through which they can challenge the actions of HCFA and local Medicare contractors in cases in which HCFA regulations, procedures, and policies were not followed properly or in which HCFA and its local contractors fail to consider or seriously misinterpret relevant data.

Since we are filing this statement following the hearing, MDMA would like to focus particular attention on two of the issues discussed during the session.

Local vs. National Coverage Decisions

First, with regard to the appropriateness of a role for regional and local HCFA contractors in determining coverage policy, MDMA firmly supports the decentralized nature of the Medicare coverage process. As the subcommittee knows, most coverage decisions are not made at national HCFA headquarters, but by the regional and local carriers with which HCFA has contracted to pay Medicare claims. Although this may seem (and sometimes is) unwieldy, this decentralization has contributed to the development and eventual nationwide adoption of advances in medical technology.

For procedures or technologies upon which HCFA has not issued a national coverage or non-coverage determination, regional and local carriers may exercise discretion in the payment of Medicare claims. HCFA authorizes these carriers to develop "local medical review policies" that define what each carrier considers to be a reasonable and necessary service. These local medical review policies, by their nature, vary from state to state.

Because the process is decentralized, medical device manufacturers, in conjunction with health professionals and patients, have opportunities to demonstrate the value of their technology to local carrier medical directors. With initial coverage in a number of states, manufacturers can then draw upon the data developed during initial coverage to demonstrate the value of their technology to HCFA. Since HCFA often wants to see data on the clinical value of a technology in the Medicare program before making a national coverage determination, this decentralized process allows manufacturers to work with amenable local carriers to develop this data in "real-world" medical settings. Without such decentralization, and without general HCFA willingness to reimburse providers broadly for studies aimed at demonstrating the clinical value of a technology to the Medicare program and its beneficiaries, manufacturers would be hard-pressed to develop a case for broad coverage of their technology.

For these reasons, MDMA urges the subcommittee to maintain a reasonable balance between local and national coverage decision-making in the Medicare program. By creating a system through which companies can petition HCFA for a national coverage determination after amassing data at the local levels, as HCFA has done in its coverage process notice, MDMA believes that HCFA will now be able to make national decisions more quickly with data developed locally.

FDA's Role in Medicare Coverage Decisions

As the subcommittee knows, the Food and Drug Administration (FDA) currently plays no formal role in the Medicare coverage determination process. HCFA recognizes FDA clearance or approval of a medical device as evidence of the device's safety and effectiveness. HCFA then focuses on determining whether Medicare coverage of a service or a device is "reasonable and necessary."

MDMA believes that "reasonable and necessary" should be further defined by rule and through HCFA guidance to health professionals, beneficiaries, and manufacturers. The phrase "reasonable and necessary," set forth in Medicare law, is too vague

to provide manufacturers with any sense of how to develop and demonstrate the value of a technology to the Medicare program. HCFA has pledged to address this issue this year, however, and MDMA looks forward to vigorous public debate on the subject.

Over the years, some observers have suggested that HCFA should not play a role in determining whether a technology should be covered under the Medicare program. These observers suggest that FDA clearance or approval of the technology should translate into automatic Medicare coverage, with HCFA's role limited to determining an appropriate level of payment for services and devices. While this may seem on the surface to be a common-sense solution to a difficult situation, the proposed cure may in fact worsen the problem.

For years, the medical device industry has worked to ensure that the FDA, in reviewing devices, adheres to its statutory mission of providing the public with a "reasonable assurance of the safety and effectiveness of devices intended for human use." 21 U.S.C. 393(b)(2)(C). MDMA and other groups have challenged FDA attempts to extend the agency's authority to reviewing the clinical utility, cost-effectiveness, or other aspects of medical devices. These decisions, we have argued, were expressly left by Congress to be decided by health professionals and the marketplace.

This Congress would be making a grave mistake if it were to give the FDA blanket authority to determine whether Medicare should cover a device. First, this would implicitly force the FDA to consider the cost of a device to the Medicare program when considering whether a medical device should be cleared or approved for marketing. Since the FDA's decisions apply beyond Medicare, the FDA's denial of a marketing application could prevent health professionals from using the technology in question to benefit any American, whether covered by Medicare, Medicaid, a private insurer, or his or her own personal funds.

To give the FDA the authority to determine what procedures are available to Medicare beneficiaries would be to consolidate far too much power in one set of hands. MDMA believes that Congress acted appropriately when it determined that the FDA should limit its reviews to safety and effectiveness considerations, and leave the determination of a technology's clinical utility and overall value to health professionals and the marketplace. MDMA hopes that this subcommittee will not seek to terminate this separation of power.

Thank you for your attention to Medicare's policies on coverage of medical services and technology, and thank you for the opportunity to share our viewpoint with the subcommittee.

Statement of National Association for Home Care

The National Association for Home Health Care (NAHC), the largest trade association representing the interests of thousands of Medicare participating home health agencies across the nation, offer these comments in support of the efforts on the Ways and Means Health Subcommittee to examine the Medicare coverage and appeals process. Since its inception in 1983, NAHC has strenuously worked with the Congress and the Health Care Financing Administration (HCFA) to secure accurate and consistent coverage determinations along with an efficient and reliable appeals process. For the Committee's consideration, we offer the following recommendations:

1. Medicare contractors should be prohibited from promulgating coverage policy.

Over the years, HCFA has authorized its claims processing contractors to develop local coverage policy in order to administer prevailing community standards of practice. However, the contractors, specifically the Regional Home Health Intermediaries (RHHIs) have increasingly acted beyond the scope of this authority in promulgating coverage policy in matters unrelated to local professional practice standards. Often the development of this policy has occurred without the knowledge of HCFA.

A prime example of this unauthorized policymaking is the home health benefit coverage standard which requires that a patient must be "confined to his home" in order to establish eligibility. The so-called homebound requirement has long been a controversial aspect of the benefit. Most recently, Congress, in the Balanced Budget Act of 1997, mandated that the Secretary of Health and Human Services engage in a study of the homebound requirement and issue a report with recommendations to Congress by October 1,1998. This mandate was chosen as an alternative to the

Administration's proposal to set inflexible frequency and duration limits on home absences into Medicare law.

Under the guise of local coverage policy authority, two of the RHHIs, without HCFA's input or direction, embarked on an effort to establish the inflexible limits with their administration of Medicare claims review while the mandated study and report was still in progress. These standards in no way reflected local community standards of medical care. Instead, these standards governed a technical coverage requirement which should be implemented and administered consistently throughout the Medicare program.

NAHC recommends that local coverage policy be limited to those few circumstances where it is necessary to address variations in professional standards of practice from one area of the country to another. Medicare contractors should be otherwise prohibited from establishing coverage policy. That function is more properly the role of this Congress and HCFA.

2. The Medicare appeals system should guarantee determinations within a reasonable time.

A significant portion of Medicare appeals relate to home health and hospice benefit determinations. While the reversal rates have been consistently high (reconsideration reversals at 30%–40%, administrative law judge (ALJ) hearing reversals in excess of 80%), the time for completion of the appeals continues to grow. When combined, the coverage length of time for processing these administrative appeals is approximately one year.

Both beneficiaries and providers of services are ill served by a process which unnecessarily takes so long. For beneficiaries, extended time with out of pocket expenditures for health care services seriously jeopardizes continued access to care. For home health agencies, the long delays increase the cost of care, disrupt the fragile cash flow of the organization and jeopardize its existence as the continued cost based reimbursement provides no opportunity for financial reserves to safeguard the provider during the appeal period.

NAHC does not support the Administration's consideration of a specialized ALJ corps in the manner it has been historically proposed. Over the years, HCFA has responded to concerns regarding the high rate of appeal reversals and the extended time for processing appeals by proposing to centralize hearings and appeals within HCFA. At one point, HCFA proposed to create a telephone based hearing system with the ALJs based at HCFA in Baltimore. This effort was exposed as an attempt to control the judge's decisions rather than to institute administrative efficiencies.

It is essential that any changes in the appeals process continue to guarantee the use of independent adjudicators who bring no bias or prejudice into their deliberations.

3. Providers of service should be afforded their own rights of appeal.

A Medicare beneficiary has a right of appeal with any adverse determination issued by Medicare and its contractors (42 USC § 1395ff). However, providers of services are limited in their independent rights of appeal to only some of the circumstances where the determinations have an adverse effect on the entity (42 USC § 1395 pp). For those instances where the provider is adversely affected without a right of appeal, the recourse for the provider is to pursue the matter as the authorized representative of the beneficiary (42 USC § 1395 ff). This approach is an unnecessary intrusion on the beneficiary.

Under 42 USC § 1395 pp, a provider of services directly can pursue an appeal where liability for the provision of non-covered care rests with the provider. The non-covered care circumstances are limited to those where the claim is denied on the basis of lack of medical necessity, homebound status, intermittent care or the conclusion that the care provided was "custodial." However, there are numerous other bases for claims denials which, while the liability rests with the provider, are only subject to appeal by the beneficiary.

The most noteworthy example of such claim denials are those based on technical conditions for payment such as requirements for physician certification of medical necessity and timeliness of Medicare billings. Where these conditions are allegedly unmet, HCFA denies the claim, prohibits the provider from charging the beneficiary, and yet allows for appeals only by the beneficiary.

NAHC recommends that the Subcommittee consider revising 42 USC § 1395 ff and 1395 pp to allow providers of services to have an independent right of appeal in all circumstances where the Medicare determination adversely affects its interests.

4. The HCFA Administrator should not have unilateral power to reject appeal determinations.

The Medicare appeals system generally does not allow HCFA to improperly interfere with the adjudicatory process. However, with respect to reimbursement related appeals, HCFA maintains an Administratively created power to disregard or reject carefully crafted determinations issued in the appeals process.

By regulation, the HCFA Administrator is authorized to unilaterally review and reject determinations issued by the Provider Reimbursement Review Board (PRRB) pursuant to its authority under 42 USC § 1395 oo. Within the last several years, the Administrator has increasingly engaged in such action forcing providers to pursue these costly appeals in federal district court. The HCFA Administrator exercises this power to reverse PRRB decisions while acting as the real party in interest that is on the losing side of a PRRB appeal. It is unacceptable for one party to an appeal to possess the power to unilaterally overturn and reject that appeal determination. Such power disregards any semblance of due process.

NAHC recommends that 42 USC § 1395 oo be amended to prohibit the HCFA Administrator from maintaining unilateral power to reverse PRRB decisions.

5. Care and services determinations by providers should not be subject to Medicare appeals.

In the testimony of Vicki Gottlich of the National Senior Citizens Law Center, it was proposed that Medicare beneficiaries should have an expedited appeal to Medicare whenever a fee-for-service provider denies services or reduces care to a patient. However, this position ignores the private relationship between the patient and the provider. It attempts to equate the decisions made by a private entity to those made by the government under the Medicare program.

Unlike managed care entities in a Medicare+Choice plan, providers of services participating in the fee-for-service plans are not surrogate Medicare administrators. In fact, these providers of services can find themselves in an adversarial relationship with Medicare. They do not control Medicare determinations. Instead, they often appeal them on behalf of beneficiaries as well as themselves.

To rewrite the principles of Medicare to subject a provider's care decisions to Medicare appeals would abrogate the insurance program concept and substitute a social program philosophy. Most care decisions by providers are unrelated to the Medicare coverage status of patients and should not be subject to Medicare review.

Statement of Pharmaceutical Research and Manufacturers of America

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit these comments on the important issue of Medicare coverage. PhRMA represents the nation's leading research-based pharmaceutical and biotechnology companies, which discover and develop the majority of new medicines used in the United States and around the world. PhRMA's member companies will invest more than $24 billion this year alone on research and development. Last year, the industry brought 39 new prescription drugs and biologicals to market, including new medicines to treat diabetes, cancer, heart disease, Parkinson's disease, HIV/AIDS, asthma, and other deadly and debilitating diseases. While Medicare does not generally cover outpatient drugs, many of the medicines discovered and developed by PhRMA member companies are reimbursed by Medicare when used in an inpatient setting, incident to physicians' services, or certain other situations.

The process and criteria for determining which treatments are covered under the Medicare program are critically important for ensuring that Medicare beneficiaries have access to high quality health care. We are very pleased that the Ways and Means Health Subcommittee, under the leadership of Chairman Thomas, is urging the Health Care Financing Administration (HCFA) to create an open and responsive process. For too long, Medicare has made its coverage decisions without adequate public input, timelines, or a process for appeals. We commend the committee for bringing attention to these coverage issues. Although HCFA's responses indicate a move in the right direction toward a better process, we are still very concerned about several issues concerning Medicare coverage of drugs and biologicals. We believe that some recent and proposed actions by HCFA and its contractors could inappropriately interfere with the practice of medicine and deprive Medicare beneficiaries of the most appropriate medical treatment.

As background for our more specific comments, the following are six principles approved by the PhRMA Board of Directors that the industry believes should guide Medicare coverage policies affecting pharmaceuticals:

- Physicians should have access to the full range of approved products to treat Medicare beneficiaries. The clinical of judgment of physicians should be respected and their discretion preserved to allow them to prescribe the most appropriate therapy for their patients.
- Medicare should cover Food and Drug Administration (FDA) approved pharmaceuticals and biologicals. There is no need for Medicare to abandon its long-standing policy of relying on FDA approval as the standard for determining which medicines will be covered when prescription medicines are in a category reimbursed by Medicare.
- Medicare should cover off-label use of approved pharmaceuticals if independent compendia or peer-reviewed literature support such use. Long-standing HCFA policy is to cover off-label uses contained in compendia or supported by the peer-reviewed medical literature. HCFA policy should not be changed to prevent or discourage these beneficial used.
- FDA-approved labeling and off-label uses included in independent national compendia or supported by peer-reviewed medical literature should be the floor for local carrier decisions. In addition, local carrier decisions should be no more restrictive than any national coverage policy or decisions. To ensure that Medicare patients, regardless of where they live, receive high-quality health care, local carriers should not restrict the use of prescription medicines in any way that conflicts with (1) FDA-approved labeling, (2) off-label uses included in independent national compendia or supported by peer-reviewed medical literature, or (3) any national policy or coverage determinations.
- Medicare beneficiaries should have immediate access to FDA-approved drugs. To promote better health, patient access to effective new medicines should not be delayed.
- Medicare reimbursement mechanisms should encourage optimal drug therapy. Individual patients' medical needs vary greatly. Thus, Medicare should reject reimbursement schemes that encourage the use of less appropriate medications in the name of cost containment.

Concerns with Current HCFA Policies and Practice

Our comments, based on the above Principles, focus on three major areas: (1) Medicare's emerging practice of allowing coverage decisions to limit the use of pharmaceuticals to less than the labeled indications approved by the Food and Drug Administration; (2) Medicare's proposed use of comparability criteria in its coverage decisionmaking; and (3) problems in the local coverage decisionmaking process employed by Medicare's contractors.

Medicare Restrictions on Use of Drugs in FDA-Approved Indications

Long-standing Medicare policy relies on Food and Drug Administration approval as the basis for Medicare coverage for Medicare-eligible drugs.[1] Since the inception of the program, when FDA approves a drug that is reimbursable by Medicare, physicians have been able to prescribe it and Medicare has paid for it. When determining whether a drug is medically "reasonable and necessary," current national Medicare policy is to consider a drug "reasonable and necessary" when it is used for one of the labeled indications approved by FDA. In addition, Medicare carriers have discretion to cover other medically accepted uses, as defined in major compendia, and must cover certain anti-cancer drugs even when used for certain off-label indications.[2] This is an appropriate policy that has worked well for years. Importantly,

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[1] Specifically, Sec. "2049.4—Reasonableness and Necessity" of the Medicare Carriers Manual states that:

Use of the drug or biological must be safe and effective and otherwise reasonable and necessary. . . . Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, you may pay for the use of an FDA approved drug or biological. . . .

Moreover, this long-standing Medicare policy was adopted in all recent HCFA attempts to publish a Medicare coverage regulation: it was included in the 1989 Notice of Proposed Rulemaking as well as in both the 1992 and 1996 drafts of the final rule that were never published.

[2] The applicable manual provision states (Medicare Carriers Manual, §2049.4 Reasonableness and Necessity):

Continued

it has ensured Medicare patients access to the FDA-approved drugs they need. (Of course, a determination of whether a drug is reasonable and necessary is made only if the drug meets other Medicare coverage requirements such as, for most drugs, not being self-administered.)

Deferring to FDA and medical compendia in determining medically acceptable uses of pharmaceuticals and biologicals is a sound policy in other respects. The FDA approval process is thorough and meticulous. HCFA and its contractors, the carriers and intermediaries, do not possess the expertise of the FDA, nor do they have sufficient staff resources to attempt to duplicate the FDA review process. In fact, to staff HCFA as would be necessary to carry out a supplemental review would be inefficient and wasteful of government resources. Medicare's policy has always been to consider all uses of pharmaceuticals and biologicals that fall within the FDA labeling to be reasonable and necessary. In fact, this policy is one of the very few Medicare coverage policies actually stated in program rules.

Although the practice of deferring to FDA expertise in this area is clear and has been HCFA policy for years, PhRMA and its members are concerned that recent actions by several Medicare carriers, as well as statements by HCFA program officials, suggest that the agency's adherence to its long-standing policy may be weakening. We strongly believe that HCFA should not abandon this policy—or even consider modifying it—without consulting the Congress prior to formal rulemaking and an opportunity for public comment. A change in this policy would pose serious threats to Medicare beneficiaries' access to FDA-approved drugs. We would quickly note that the agency has not initiated rulemaking to change the policy, and the Medicare Carrier's Manual remains unchanged.

With the personnel and organizational changes that have accompanied HCFA's reorganization, combined with new activity on the part of some of the local carriers, HCFA needs to reaffirm its long-standing policies concerning Medicare coverage of pharmaceuticals with respect to labeled and off-label indications. On several occasions, PhRMA and its members have urged HCFA—unsuccessfully—to take this action. This could be done simply—for example, through a Program Memorandum or other formal communication to carriers and fiscal intermediaries. In doing so, HCFA should state clearly that FDA-approved labeling and medical literature are the basis for determining when a drug is medically necessary, and that this policy applies to both local and national decisions about when the use of a drug is "reasonable and necessary." It is regrettable that the agency now seems willing to vacate a policy that has been in place since the program's inception that underpins the high quality of health care delivered to Medicare patients. Strong and clear action is necessary to ensure that Medicare beneficiaries have access to the full range of approved drugs for all approved indications. HCFA should continue to rely on the expertise of the FDA for decisions regarding the appropriate use of drugs, and upon the clinical judgment of physicians concerning their use for individual patients. Medicare does not now, and will not in the foreseeable future, have the expertise to make independent medical determinations about the appropriate use of pharmaceuticals. *PhRMA and its members urge the Committee to take legislative action, if necessary, to safeguard this important policy.*

Inappropriate Use of Comparability Criteria in Coverage Decisions

As part of its new coverage proposal, HCFA also is considering establishing "comparability" as a new criterion for Medicare coverage. Under this standard, if HCFA determined two drugs or biologicals to be therapeutically equivalent, both would be reimbursed at the level of the lower-cost medicine. PhRMA and its members strongly oppose the application of comparability or "least costly alternative" determinations. We believe that, in decisionmaking about what medicines to use to treat a specific individual, only physicians are qualified to determine when two different medicines are likely to provide equal therapeutic benefit. HCFA and its contractors should not impose their views on these important doctor-patient decisions. Moreover, if a physician determines that a specific drug is best for the patient, whether or not that drug is the least costly alternative, reimbursement should be based on the price of that drug, not the price of the least costly alternative. *Allowing HCFA*

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. . . Unlabeled uses of FDA-approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen [are covered] if the use is supported by one of the approved medical compendia.

this comparability authority would lower the quality of care provided to Medicare patients.

Implementation of a comparability criterion implicitly assumes that two *different* chemical entities are essentially the same. We would emphasize that a process currently exists under which the FDA determines generic bio-equivalence of drugs with the same active ingredient. In addition, special Medicare rules are used to determine how much the program will reimburse for generically bio-equivalent drugs. For HCFA to go beyond these well established procedures for products that are not identical has no basis in science, medical practice or law.

Moreover, we are concerned about the consequences for patients of letting HCFA and its contractors run free with comparability authority. Similar drugs can have very different effects in different patients. A particular drug within a multi-drug therapeutic class may be the best choice for one patient, but not for other patients with the same condition. These are exactly the decisions that should be reserved solely for the physician charged with treating a patient. The application of a comparability standard could lead to de facto denial of coverage for many prescription medicines that uniquely benefit Medicare patients. If Medicare reimbursement of providers is set at the level of the least costly treatment, payment policy—in conflict with best medical practice—will create strong incentives for physicians and providers not to use certain medicines, even when they are most appropriate for their patients. Clearly physicians and other providers would be inclined not to use medicines that cost them more than Medicare reimburses, even when the more costly medicine is more effective and more appropriate for the patient and, in many cases, more cost-effective overall. *Because of its potential to lower the quality of patient care, we urge you to block HCFA's use of a comparability standard for determining Medicare coverage of drugs and biologicals.*

Serious Problems in Local Coverage Process

We are particularly concerned that HCFA's current plan for revising its coverage process appears to exclude local coverage decisions. The overwhelming majority of Medicare coverage policies are local, not national, and it is unlikely that this will change in the near future. Our concern on this critical matter has been heightened by what our members see as new restrictions being imposed by Medicare's local carriers. There is a growing list of instances in which one carrier, or a group of carriers (for example, those in a particular regional office area), have established restrictive policies. We would note that these actions appear to occur most frequently with newer, more expensive drugs, raising the possibility that HCFA and its carriers are turning their backs on long-standing Medicare policy strictly for budget-cutting purposes. These actions already are depriving Medicare patients in certain areas of beneficial drug treatments available to beneficiaries in other areas and to patients enrolled in private health plans.

Carriers' restrictive policies are taking many forms. Sometimes, as noted, they deny coverage of drugs and biologicals for not being reasonable and necessary even when they are used fully consistent with FDA-approved indications or a listing in the medical compendia. Other times, they make decisions not to cover a particular drug because they consider it to be precluded from coverage by statutory restrictions on preventive treatments or drugs that are self-administered. Thus, for example, some carriers do not cover certain injectable drugs important to many cancer patients undergoing chemotherapy because *some* patients *could* administer the injections themselves—even though the *usual* means of administration is not by the patient. In another situation, carriers are withholding coverage because the drug can be used to reduce complications from surgery, such as transfusions. The carriers incorrectly and inappropriately deem this use to be preventive.

These brief examples are only illustrative of some of the inappropriate and indefensible actions by Medicare carriers in recent months. We are disturbed not only by the seriousness and prevalence of these problems, but by the fact that HCFA continues to ignore them. Despite pleas from PhRMA and its member companies and many other associations representing patients, physicians, providers and manufacturers, HCFA has continued to refuse to address these concerns in its review of the coverage process. As we have already noted, in the case of pharmaceuticals and biologicals, many of the inappropriate carrier decisions could be avoided if HCFA were, with respect to drugs and biologicals, to reaffirm the reliance on FDA labeling and the medical compendia for Medicare coverage decisions. At a minimum, this should be done, and done quickly. But this alone would not be sufficient to address the many local problems restricting coverage of pharmaceuticals, biologicals and other health services. Unlike the national coverage process, which is not governed by any existing regulations or other formal policy, at the local level, HCFA's carrier

manual requires a consultation process. In certain carrier areas, the local process—a Carrier Advisory Committee (CAC)—appears to work reasonably well. In other areas, the process is pro forma, at best. *Because HCFA has failed to do so, Congress should review and tighten the requirements governing the local coverage process to ensure that local decisions are made in an open and consultative manner, and in full compliance with national policies. Moreover, given the importance of local coverage decisions in determining what treatments are actually available to Medicare beneficiaries, actions to improve the local process must be initiated as quickly as possible, as part of current reforms.*

In conclusion, PhRMA believes that the current process for making Medicare coverage decisions at both the local and national level is closed and unresponsive to the public. The proposals that HCFA has made thus far do not go nearly far enough to address these and other problems. HCFA must publish both process and substantive requirements for establishing Medicare coverage through notice and comment rulemaking. HCFA's process for making coverage decisions should provide for public input at all stages, must include mandatory time frames, and must provide an opportunity for appeal. Moreover, the backbone of any new HCFA process must be reliance on FDA approval and medical compendia for coverage determinations, rejection of a comparability criteria, and inclusion of local carriers in decision-making.

PhRMA believes that the proposed new process and criteria for coverage, as currently conceived by HCFA, risk lowering the quality of health care received by Medicare beneficiaries. We are particularly concerned that, if HCFA places new restrictions on patient access to pharmaceuticals and biologicals as planned, Medicare's elderly and disabled beneficiaries may be harmed.

We thank you for the opportunity to submit these comments.

Statement of George A. Sample, MD, FCCP, Society of Critical Care Medicine, Anaheim, California

I appreciate this opportunity to provide testimony on behalf of the Society of Critical Care Medicine (SCCM) to the Health Subcommittee of the House Ways and Means Committee with respect to certain regulatory issues facing physicians who provide critical care services to Medicare patients. In existence since 1970, SCCM represents over 6,400 physicians specializing in the delivery of medical care services to critically ill or injured patients.

SCCM has previously has engaged in productive discussions with HCFA on regulatory issues. For example, immediately after the Physician Fee Schedule was implemented in 1992, SCCM was engaged in extensive discussions with HCFA officials over the significant undervaluation of critical care services. Critical care services had been ignored in the establishment of the Fee Schedule. During these conversations, there was agreement between HCFA and SCCM that critical care services essentially are medical management services whereby the critical care specialist is evaluating and manipulating complex databases to prevent or treat single or multiple vital organ system failure. The exact procedures to be bundle into payment for the critical care services were carefully negotiated in establishing an appropriate fee. There was much discussion and agreement that critical care services were *not* "emergency" or "crash" services. Moreover, the concept that these codes are only "emergency" codes is contrary to the entire approach of the critical care physician as the manager of the care of these patients.

In 1994, HCFA and SCCM coordinated national professional critical care organizations to address carrier medical directors' inappropriate interpretation of the critical care codes as "emergency" services. HCFA formed a task force of carrier medical directors to investigate the problem, with Marjorie Kanof, M.D., then-carrier medical director from Massachusetts chairing the task force. SCCM felt that the task force meetings were very productive and that once again HCFA officials and SCCM were in agreement as to the nature of critical care services as medical management codes. Indeed, Dr. Kanof clearly acknowledged that critical care services could be provided to "hemodynamically stable" patients and wanted to be informed of any carrier who was not adhering to this standard. As a result of the task force meetings, HCFA issued a program memorandum on February 10, 1995, signed by Elizabeth Cusick (the "Cusick memo") clarifying that critical care codes are management codes that could be used to describe services provided to prevent a patient from experiencing a single or multiple vital organ system failure. Moreover, the Cusick memo acknowledged that some carriers had required there to be a medical emer-

gency for critical care to be billed but "[s]uch an interpretation is too narrow and restricts the use of the critical care codes inappropriately."

Now, once again, carrier medical directors are applying inappropriate, narrow interpretations to the critical care codes in contradiction to the Cusick memo, even when it is brought squarely to their attention. You will be receiving testimony from individual critical care physicians who will confirm that carrier medical directors are not abiding by the Cusick memo. HCFA once again has formed a task force to investigate the situation, and SCCM is working closely and productively with this task force.

Just this past year, SCCM is aware of carriers covering the states of Maryland, Delaware, D.C., Texas, Idaho, and Tennessee attempting to implement local medical review policies (LMRPs) on critical care services that were in direct contradiction to the Cusick memo. At the very least, the LMRPs would have limited the use of the critical care codes to medical emergencies. Fortunately, when SCCM brought these LMRPs to the attention of HCFA, agency officials instructed the carriers not to implement LMRPs on critical care until the task force concludes its work. We would be remiss if we did not acknowledge the cooperation of Trailblazer's, which has worked with us toward a common goal of improving the conditions for carriers and physicians since that time.

What is even more confounding to the Society and to practicing critical care physicians than the above mentioned LMRPs and the carriers' use of inconsistent standards is the fact that regardless of the standards that the carriers are using, there is no attempt to communicate these standards to critical care physicians until after an audit takes place and the carrier is sometimes demanding reimbursement of a significant overpayment. Many carriers are conducting "post-Cusick memo" audits of medical records where it appears that they are again interpreting the critical care codes as "crash" codes. In these audits, carrier medical directors are alleging that a large percentage of critical care services are "medically unnecessary" by using criteria that had never been communicated to the physicians.

Further, studies have shown that involvement of the critical care specialist in a patient's care can reduce length of stay in the ICU and the hospital, reduce patient mortality, and reduce health care costs. Nevertheless, several carriers are defining critical care services so narrowly that the majority of the services provided by the critical care physician would be deemed by the carrier as not medically necessary for the Medicare patient. We are concerned that these narrow carrier interpretations will produce a chilling effect on the delivery of critical care services. The net result could be that patient care will suffer and costs will escalate.

Some carriers are denying critical care services if the medical record does not denote specifically the time spent providing critical care services. In many of these cases, it is absolutely clear from the substance of the physician note in the medical record that over 30 minutes of care to the patient was provided. While it is HCFA's view that the necessity of actual time being documented in the physician note is required in the Medicare carrier manual, it is not emphasized or clearly written, and, more importantly, is not typically communicated to physicians.

Not only are the practicing physicians unaware of this rule, but some carrier medical directors are as well. In Idaho, the carrier medical director stated in a letter to an audited physician that ". . . notation of time was not a necessity." Additionally, if the substance of the audited medical record supports the fact that over 30 minutes of care *was provided*, why should payment be denied just because actual time was not recorded?

A 1995 letter from Celeste Kirschner, Secretary of the AMA CPT Editorial Panel supports the position that the substance of the note could act as a proxy for a listing of the exact time. Despite the support of the AMA CPT Editorial Panel and some carrier medical directors, other carrier medical directors will deny critical care claims without a notation of exact time and assess physicians hundreds of thousands of dollars through claims extrapolation. At a minimum, physicians and carriers should be thoroughly educated on proper documentation nuances before a repayment is sought for services which were truly provided.

Just as the absence of time notation is an automatic denial of a claim, so is the presence of the word "stable" in the minds of many chart reviewers. As an example, a critically ill patient on the fifth day of his/her sepsis, receiving vasoactive medication (Levophed, epinephrine) and on ventilator support, would be considered "stable," because no changes were made in the patient's life sustaining support. In fact, no changes are made because the patient remains too ill and too tenuous to wean any support, yet not progressing or deteriorating either. The purpose of the Cusick memo was, in part, to inform carriers that critical care may be provided in clinical situations such as mentioned above. Further, the Cusick memo clearly states that

critical care may be provided to *prevent* a patient from having single or multiple organ system failure.

Taken to its absurdity, a patient with a DNR order has been deemed by a carrier medical director to be ineligible for reimbursement of critical care services. To the carrier, a DNR implies that the physician is either not actively managing that patient's care or the patient's condition does not justify the provision of critical care services. As you will hear, this is not an appropriate conclusion.

Carriers also appear confused about critical care services provided within a global surgery period. The carriers do not appear to understand the concept of concurrent care that HCFA resolved in 1992. The surgeon continues to provide standard postoperative care to patients in the ICU, however, the critical care physician is managing the care of a particular problem or problems for the patient. Both the surgeon and the critical care physician are providing medically necessary services.

Most carrier medical directors are making no attempt to consult with critical care physicians in their area to develop reasonable criteria and documentation guidelines before these carriers audit a critical care physician, and potentially seek overpayment of assessments of hundreds of thousands of dollars. The medical directors are either unaware or defiant of the Cusick memo.

For example, the South Carolina carrier medical director emphasizes in the Medicare Bulletin that the carrier physician education function is critical and that the carrier notifies doctors when their billing pattern varies substantially from that of their peers. As you will see from testimony here today, the South Carolina carrier made no attempt to inform critical care physicians regarding the criteria that would be used to audit critical care services in that state. Instead, the carrier appeared to use an arbitrary standard. We are also concerned that the medical director seemed to issue a prospective announcement in the Medicare Bulletin that in 1997 he expected to recoup through audits $200 million.

While we are encouraged by the direction and tone of our meetings with HCFA in developing further instructions to the carriers on the proper interpretation of the critical care services and the input from Trailblazer's, we have received little or no relief from HCFA relative to our concerns about how carriers currently are conducting audits of critical care services with the wrong interpretation of these codes and without providing physicians with any prior notice of their standards.

Thus, we have the following recommendations for HCFA:

- HCFA should issue another clarifying memorandum to carrier medical directors explaining that the critical care codes are not simply "crash" codes.
- Carrier audits of critical care services, except for egregious situations, should be suspended until this clarifying memorandum can be issued.
- Past audits where the carrier used standards in contradiction to the Cusick memo should be reopened.
- HCFA should require carriers to conduct educational programs on critical care billing once the new memorandum is issued. The education should be based on the national standards. The professional critical care organizations would like to be part of this process, working closely with HCFA and the carriers.
- Carriers who purposely disregard a HCFA standard and subject physicians to erroneous reviews should be subject to some type of sanction by HCFA. The carriers should not be judged solely by how much money they recoup. There must be some forum established within HCFA for HCFA to hear and act upon complaints about carrier consistency with national standards. Physician input should be considered in annual carrier performance reviews.
- Carriers should be more circumspect in their use of extrapolation to levy six figure overpayment assessments. Prior to proper educational programs, carriers should not use extrapolation where audits reveal simply honest mistakes in documentation or interpretation.
- A claim should not be denied simply because the exact time was not recorded, because the word stable was used, because the words DNR appear, or because the patient is post surgery. Auditors must have sufficient clinical knowledge and must review the complete record so that they can determine from the substance of a note that over 30 minutes of care was clearly provided or that the patient's condition may have been hemodynamically stable because the critical care physician was closely monitoring the patient's condition. In addition, a critical care physician can actively manage the care of a DNR patient who requires critical care services and provide medically necessary services to post surgical patients.
- Billing patterns of critical care physicians should be compared to other critical care physicians.

The system only works if physicians believe they are being treated fairly. The members of the Society of Critical Care Medicine would welcome an opportunity to work with the Health Subcommittee to address these important issues. Thank you.

SUNDANCE REHABILITATION CORPORATION
DALLAS, TX 75240
May 6, 1999

A. L. Singleton,
Chief of Staff,
Committee on Ways and Means
U.S. House of Representatives
1102 Longworth House Office Building
Washington, D.C. 20525

I would like to thank Congressman Bill Thomas for your most recent efforts to provide reasonable time frames for the appeals of claims for services provided to Medicare recipients. Denied claims may take over 4 years to be resolved through the various steps of the appeal process.

The process in question lacks fairness to the provider community. Please consider the following points.

1. Services denied payment by Fiscal Intermediaries and subsequently deemed payable by an Administrative Law Judge continue to be denied payment when such services are provided. This creates great frustration for the service providers and the Administrative Law Judge. The appeals process becomes burdened with issues that have been ruled on numerous occasions.

2. On average, I win 95% of the appeals that reach the Administrative Law Judge level. I do not believe that this percentage is significantly different than other providers. Based on this level of claims being overturned, it would lead one to view the appeals process as a system that delays payment for services not as a system that determines the appropriateness of the service.

While your current legislation provides a much more reasonable time frame for claims to reach the Administrative Law Judge level, without similar time frames for this level, the backlog of claims will remain.

You may also wish to consider that part of a viable solution rests in fewer claims needing the appeals process for resolution. This could be accomplished by HCFA taking a clear position on services rather than allowing the various Fiscal Intermediaries to create coverage policy. A uniform approach to this issue ensures that a greater consistency of the Medicare program for recipients, providers and regulators.

Another solution, in reducing the number of claims seeking resolution through the appeal process, is the charging of interest on the withheld payment. When claims are denied, payment is not made for the service or goods the Medicare recipient has received. When the claim is resolved, years later, payment is for the original billing without any adjustment for interest. The impact of this practice is clear. At the same time, when a provider owes money back to the Medicare program, interest is charged on any unpaid balance, at an interest rate of nearly 14%. I fail to see the fairness in this approach.

When Fiscal Intermediaries are faced with the prospect of paying interest for the abusive manner in which claims are denied, the process will improve.

Currently, I have over $3,000,000.00 in claims at some step in the appeals process. I will win 95% or more of these disputes. I also realize that for every claim overturned in my favor I have lost the cost of that money over the years. In addition to the cost of money, are the expenses of the hearing process and the lost time of the staff required to present the claims. I also realize that if I do not pursue payment, I could be charged with fraudulent billing practices.

Sincerely,

DAVID KNIESS,
President

TRANSAMERICA OCCIDENTAL LIFE INSURANCE COMPANY
TRANSAMERICA CENTER
LOS ANGELES, CA 90015–2211
May 4, 1999

Congressman William Thomas
Committee on Ways and Means
1136 Longworth House Building
Washington D.C. 20515

Dear Congressman Thomas:

As the Chief Medicare Officer for Transamerica Occidental Life Insurance Company, the Southern California Medicare Part B carrier, I would like to respond to the testimony given by Frank J. Kiesner, President and CEO of Oncotech Inc., to the House Ways and Means Committee, Subcommittee on Health, on April 22, 1999.

Transamerica Occidental has been the Part B administrator in the Southern California area since the inception of the Medicare Program. Under our contract with the federal government, Transamerica Occidental follows specific rules and regulations outlined by the Health Care Financing Administration (HCFA) in processing Medicare claims. Our Medicare area currently processes close to 28 million claims a year, serving 1.2 beneficiaries and 25,000 providers. Many thousands of these processed claims are for cancer tests and treatments.

Oncotech produces a cancer test called the Extreme Drug Resistance (EDR) test that determines if a patient is extremely resistant to a chemotherapy drug. While we are certainly eager to see effective, new treatments and tests for cancer patients, as more fully discussed below our opinion is that Oncotech's test is still considered experimental. Therefore, the company's claims have been denied.

In certain instances, local carriers are given latitude in determining whether new tests and treatments fall within the prescribed HCFA guidelines. When this occurs, as is the case with the EDR test, we rely upon independent, outside medical consultants to advise us about the effectiveness of the test or treatment in question. These consultants are licensed practitioners who are board certified in their field of expertise. Their names are deliberately not revealed to avoid external influences by product or pharmaceutical manufacturers.

Our discussions with these medical experts, along with our own medical department's evaluation of current scientific literature, have led us to conclude that the EDR test is virtually the same as a drug chemosensitivity test. Drug chemosensitivity tests are still considered "investigational" by HCFA and not eligible for payment. At this time, the scientific evidence does not prove EDR's effectiveness in the diagnosis or treatment of the majority of oncology patients.

Oncotech was notified several times about our decision and the rationale for it. In addition, all of Transamerica's decisions are published in our Medicare newsletter that is distributed to all providers. In the future, if HCFA determines that chemosensitivity and/or EDR testing is reasonable and necessary and revises its national policy, we would change our policy as well. In addition, if new, scientific data leads our consultant experts to view EDR as a test covered under Medicare, we would change our local policy. This change would be communicated in our newsletter to providers.

In his testimony, Mr. Kiesner also makes a number of recommendations regarding local Medicare processes and policies. Although not addressed in this letter, we would be happy to discuss any of the other points raised in his letter or to provide additional specific information about how we arrived at our decision related to the EDR test.

Sincerely,

GEORGE E. GARCIA
Chief Medicare Officer

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